Docket for 03-1454

(24)

No. 03-1454
Title: John D. Ashcroft, Attorney General, et al., Petitioners
v.
Angel McClary Raich, et al.
Docketed: April 20, 2004
Lower Ct: United States Court of Appeals for the Ninth Circuit
Case Nos.: (03-15481)
Decision Date: December 16, 2003
Rehearing Denied: February 25, 2004
Questions Presented

~~Date~~	~~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~~~~~
Apr 20 2004	Petition for a writ of certiorari filed. (Response due May 20, 2004)
Apr 20 2004	Appendix of John D. Ashcroft, Attorney General, et al. filed.
May 17 2004	Order extending time to file response to petition to and including June 4, 2004.
May 28 2004	Order further extending time to file response to petition to and including June 7, 2004.
Jun 7 2004	Brief of respondents Angel McClary Raich, et al. in opposition filed.
Jun 8 2004	DISTRIBUTED for Conference of June 24, 2004.
Jun 10 2004	Reply of petitioners John D. Ashcroft, Attorney General, et al. filed. (Distributed)
Jun 18 2004	Letter from Solicitor General received. (Distributed)
Jun 28 2004	Petition GRANTED.
Aug 11 2004	Joint appendix filed.
Aug 11 2004	Brief of petitioners John D. Ashcroft, Attorney General, et al. filed.
Aug 11 2004	Brief amicus curiae of Pacific Legal Foundation filed.
Aug 11 2004	Brief amici curiae of Robert L. DuPont, Peter B. Bensinger, and Herbert Kleber filed.
Aug 12 2004	Brief amici curiae of Drug Free America Foundation, et al. filed.
Aug 12 2004	Brief amici curiae of Mark E. Souder, et al. filed.
Aug 12 2004	Brief amicus curiae of Community Rights Counsel filed.
Sep 7 2004	Extension of time within which to file respondents' brief on the merits to and including September 29, 2004.
Sep 27 2004	Further extension of time within which to file respondents' brief on the merits to and including October 13, 2004.
Sep 27 2004	Motion for leave to file amicus brief filed by Drug Watch International.
Sep 29 2004	SET FOR ARGUMENT ON Monday, November 29, 2004.
Sep 30 2004	CIRCULATED.
Oct 13 2004	Brief of respondents Angel McClary Raich, et al. filed. (Distributed)
Oct 13 2004	Brief amici curiae of California Nurses Association and DKT Liberty Project filed. (Distributed)
Oct 13 2004	Brief amici curiae of Alabama, Louisiana, and Mississippi filed. (Distributed)
Oct 13 2004	Brief amicus curiae of Institute for Justice filed. (Distributed)
Oct 13 2004	Brief amicus curiae of Constitutional Law Scholars filed. (Distributed)
Oct 13 2004	Brief amici curiae of California, Maryland, and Washington filed. (Distributed)
Oct 13 2004	Brief amicus curiae of Cato Institute filed. (Distributed).

Oct 13 2004	Brief amici curiae of Leukemia & Lymphoma Society, et al. filed. (Distributed)
Oct 13 2004	Brief amici curiae of Marijuana Policy Project and Rick Doblin filed. (Distributed).I
Oct 13 2004	Brief amici curiae of Lymphoma Foundation of America, et al. filed. (Distributed)
Oct 13 2004	Brief amicus curiae of Reason Foundation filed. (Distributed)
Oct 13 2004	Brief amici curiae of National Organization for the Reform of Marijuana Laws, et al. filed. (Distributed)
Oct 28 2004	Record received from U.S.C.A. 9th Circuit. (1 envelope)
Nov 1 2004	Record received from U.S.D.C. - Northern Dist. of California. (1 box)
Nov 8 2004	Motion for leave to file amicus brief filed by Drug Watch International DENIED.
Nov 17 2004	Reply of petitioners John D. Ashcroft, Attorney General, et al. filed. (Distributed)
Nov 29 2004	Argued. For petitioners: Paul D. Clement, Acting Solicitor General, Department of Justice, Washington, D.C. For respondents: Randy E. Barnett, Boston, Mass.

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No.

In the Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate cultivation and possession of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use.

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States, and Karen P. Tandy, Administrator of the Drug Enforcement Administration.

Respondents are Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two.

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In the Supreme Court of the United States

No.

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
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v.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Attorney General of the United States and the Administrator of the Drug Enforcement Administration, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-43a)[1] is reported at 352 F.3d 1222. The order of the district court denying respondents' motion for a preliminary injunction (App. 44a-69a) is reported at 248 F. Supp. 2d 918.

[1] "App." refers to the separately bound appendix to the petition for a writ of certiorari.

JURISDICTION

The judgment of the court of appeals was entered on December 16, 2003. A petition for rehearing was denied on February 25, 2004 (App. 70a-71a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

The Commerce Clause of the United States Constitution, Article I, Section 8, Clause 3, provides: "The Congress shall have Power * * * To regulate Commerce * * * among the several States."

STATEMENT

1. a. The Controlled Substances Act (CSA or Act), 21 U.S.C. 801 *et seq.*, establishes a comprehensive federal scheme to regulate the market in controlled substances. The CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1). The CSA similarly makes it a crime to possess any controlled substance except as authorized by the Act. 21 U.S.C. 844(a). The CSA thus establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 6 (1970). To effectuate that closed system, the CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal." *United States* v. *Moore*, 423 U.S. 122, 141 (1975) (quoting H.R. Rep. No. 1444, *supra*, at 3). Violations of the CSA are subject to criminal and civil penalties and may be enjoined. 21 U.S.C. 841-863, 882(a).

The restrictions that the CSA places on the manufacture, distribution, and possession of a controlled substance depend upon the schedule in which the drug

has been placed. 21 U.S.C. 821-829. Since Congress enacted the CSA in 1970, marijuana and tetrahydrocannabinols have been classified as schedule I controlled substances. See Pub. L. No. 91-513, Tit. II, § 202(c), 84 Stat. 1249 (schedule I(c)(10) and (17)); 21 U.S.C. 812(c) (schedule I(c)(10) and (17)).[2]

A drug is listed in schedule I, the most restrictive schedule, if it has "has a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C). Under the CSA, it is unlawful to manufacture, distribute, dispense, or possess a schedule I drug, except as part of a strictly controlled research project that has been registered with the Drug Enforcement Administration (DEA) and approved by the Food and Drug Administration (FDA). 21 U.S.C. 823, 841(a)(1), 844(a); *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489-490, 492 (2001). By contrast, drugs listed in schedules II through V may be dispensed and prescribed for medical use. Physicians, pharmacies, and other legitimate handlers of drugs listed in schedules II through V must, however, comply with stringent statutory and regulatory provisions that control the manufacture and distribution of such drugs. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306.

b. The CSA contains congressional findings and declarations regarding the effects of intrastate drug

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[2] Marijuana is defined under the CSA to include all parts of the cannabis plant and anything made therefrom, except for the mature stalks, fiber produced from the stalks, sterilized seeds, and oil from the seeds. 21 U.S.C. 802(16). Marijuana has been found to contain at least 483 separate chemicals, among which, delta-9-tetrahdyrocannabinol (delta-9-THC) is the primary psychoactive component. 66 Fed. Reg. 20,038, 20,041 (2001).

activity on interstate commerce. 21 U.S.C. 801. Congress found:

> Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—
>
> (A) after manufacture, many controlled substances are transported in interstate commerce,
>
> (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and
>
> (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

21 U.S.C. 801(3). Congress similarly found that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances," 21 U.S.C. 801(4); that "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate," and "[t]hus, it is not feasible to distinguish" between such substances "in terms of controls," 21 U.S.C. 801(5); and that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic," 21 U.S.C. 801(6). Congress also found that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and

general welfare of the American people." 21 U.S.C. 801(2).

2. On October 9, 2002, respondents filed suit in the United States District Court for the Northern District of California against John Ashcroft, the Attorney General of the United States, and Asa Hutchinson, then the Administrator of the Drug Enforcement Administration, seeking injunctive and declaratory relief barring them from enforcing the CSA as applied to their conduct. The complaint alleges that respondents Angel McClary Raich and Diane Monson are California citizens who use marijuana for medical purposes based on the recommendations of their physicians. Such use is exempted from the coverage of California's criminal drug laws. App. 1a-2a, 45a; see California's Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West Supp. 2004).

Raich, a resident of Oakland, California, alleges that she suffers from numerous severe and debilitating medical conditions for which marijuana alone provides relief, and that her physicians recommend that she "medicate" with marijuana every two hours. App. 5a, 76a, 79a. Raich alleges that she is unable to cultivate her own marijuana and that she obtains marijuana free of charge from two "caregivers," respondents John Doe Number One and John Doe Number Two, who are also residents of Oakland, California, and who sued anonymously to protect Raich's marijuana supply. *Id.* at 5a, 14a n.3, 77a-78a. Although the Does cultivate the marijuana, Raich processes some of the marijuana into cannabis oils, balm, and foods. *Id.* at 5a.

Diane Monson, a resident of Butte County, California, alleges that she suffers from severe chronic back pain and constant, painful muscle spasms, and that she has been using marijuana as a medication for more than

five years. App. 5a, 76a-77a, 80a-81a. Monson alleges that, in August 2002, federal agents came to her home and seized her six marijuana plants, over the objection of the Butte County District Attorney. *Id.* at 76a-77a.

Respondents' suit sought a preliminary injunction to bar the government from enforcing the Controlled Substances Act against them to the extent that it prevents Raich and Monson from possessing, cultivating, and processing marijuana for their purported medical use, and to the extent that it prevents the John Doe respondents from cultivating marijuana and providing it to Raich for her purported medical use. App. 89a-91a. Respondents urged that the CSA, as applied to their conduct, is unconstitutional and conflicts with the purported "doctrine of medical necessity." *Id.* at 6a.

On March 4, 2003, the district court denied the motion for a preliminary injunction, concluding that "the weight of precedent precludes a finding of likelihood of success on the merits." App. 45a.

3. A divided panel of the court of appeals reversed and remanded. App. 1a-43a.

a. The court of appeals concluded that respondents "have demonstrated a strong likelihood of success on their claim that, as applied to them, the CSA is an unconstitutional exercise of Congress's Commerce Clause authority." App. 9a. The court observed that its previous decisions that had uniformly rejected Commerce Clause challenges to the CSA were not controlling, because none of those decisions "involved the use, possession, or cultivation of marijuana for medical purposes." *Id.* at 10a.

The court found that the "intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician" "constitutes a separate and distinct class of activities"

that is beyond Congress's power to regulate under the Commerce Clause. App. 11a (emphasis omitted). The court found that class "different in kind from drug trafficking," reasoning that "this limited use is clearly distinct from the broader illicit drug market— as well as any broader commercial market for medicinal marijuana—insofar as the medical marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." *Ibid.*

The court of appeals also reasoned that "[t]he cultivation, possession, and use of marijuana for medicinal purposes and not for exchange or distribution is not properly characterized as commercial or economic activity." App. 14a. The court accordingly found "not applicable" the "aggregation principle" of *Wickard* v. *Filburn*, 317 U.S. 111 (1942), which allows for consideration of the cumulative impact on interstate commerce of individual instances of regulated conduct (in *Wickard*, the cultivation of wheat). App. 15a. The court also rejected the importance of Congress's findings in the CSA regarding the effects of intrastate drug activity on interstate commerce, reasoning that "[t]he findings are not specific to marijuana, much less intrastate medicinal use of marijuana that is not bought or sold and the use of which is based on the recommendation of a physician," and that in any event such findings should be taken "with a grain of salt." *Id.* at 19a-20a. Finally, the court concluded that the hardship of the parties and public interest factors "tip sharply" in favor of the entry of a preliminary injunction. *Id.* at 24a.

b. Judge Beam dissented. App. 26a-43a. In his view, "[i]t is simply impossible to distinguish the relevant conduct surrounding the cultivation and use of the marijuana crop at issue in this case from the cultivation

and use of the wheat crop that affected interstate commerce in *Wickard* v. *Filburn*, [*supra*]." *Id.* at 26a. The dissent explained that the court of appeals' approach ignored "the fungible, economic nature of the substance at issue—marijuana plants—for which there is a well-established and variable interstate market, albeit an illegal one under federal law." *Id.* at 34a; accord *id.* at 34a-35a (Respondents "are growing and/or using a fungible crop which *could* be sold in the marketplace, and which is also being used for medicinal purposes in place of other drugs which would have to be purchased in the marketplace.").

Judge Beam also concluded that Congress's power to regulate respondents' activities is essential to Congress's ability to regulate "the larger commercial activity" covered by the CSA. App. 36a. He reasoned that, "[i]f Congress cannot reach individual narcotics growers, possessors, and users, its overall statutory scheme will be totally undermined." *Id.* at 38a. Judge Beam also observed that the court's decision to carve out from Congress's general regulatory scheme individual instances of activity based on their ostensibly *de minimis* relation to commerce conflicts with the decisions of *Proyect* v. *United States*, 101 F.3d 11 (2d Cir. 1996), and *United States* v. *Leshuk*, 65 F.3d 1105 (4th Cir. 1995). App. 35a-37a.

REASONS FOR GRANTING THE PETITION

The Court of Appeals for the Ninth Circuit has held that the Controlled Substances Act cannot constitutionally be applied to the manufacture, possession, and distribution without charge of marijuana for purported medicinal use. The court of appeals' partial invalidation of that Act of Congress is erroneous and seriously undermines Congress's comprehensive

scheme for the regulation of dangerous drugs. The court of appeals' reliance on the purported medical purposes of respondents' activities also conflicts with this Court's decision in *Oakland Cannabis*, 532 U.S. at 491, 494, which held that the CSA does not countenance any medical use of marijuana. The Ninth Circuit's decision, moreover, cannot be reconciled with the decisions of other courts of appeals that have held that Congress has the power under the Commerce Clause to prohibit the manufacture or possession of controlled substances, including marijuana, for personal use.

A. THE NINTH CIRCUIT ERRED IN DECLARING THAT CONGRESS CANNOT REGULATE THE MANUFACTURE, POSSESSION, AND FREE DISTRIBUTION OF MARIJUANA

1. The Commerce Clause grants Congress the power to regulate a class of activities that substantially affects commerce, regardless of whether an individual instance within the class has a significant effect on interstate commerce. "[W]here a *general regulatory statute bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under that statute is of no consequence." *United States* v. *Lopez*, 514 U.S. 549, 558 (1995) (quoting *Maryland* v. *Wirtz*, 392 U.S. 183, 197 n.27 (1968)); accord *Perez* v. *United States*, 402 U.S. 146, 154 (1971) ("[w]here the *class of activities* is regulated and that *class* is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class") (quoting *Wirtz*, 392 U.S. at 193); *Citizens Bank* v. *Alafabco, Inc.*, 539 U.S. 52, 56-57 (2003) (per curiam).

For example, in *Wickard* v. *Filburn*, 317 U.S. 111 (1942), the Court upheld federal regulation of wheat grown and consumed on a family farm in order to

control the volume of wheat moving in interstate and foreign commerce. *Wickard* establishes that activity occurring within a market is subject to Congress's commerce power even when the activity may itself not be commercial. This Court explained in *United States* v. *Lopez*, *supra*, that the production of wheat that Congress chose to regulate in *Wickard* is economic activity even though it was produced for personal use and "may not be regarded as commerce." *Lopez*, 514 U.S. at 556 (quoting *Wickard*, 317 U.S. at 125). In distinguishing the statute in *Wickard* from the Gun-Free School Zones Act of 1990, 18 U.S.C. 922(q), at issue in *Lopez*, the Court explained that "*Wickard* * * * involved economic activity in a way that the possession of a gun in a school zone does not." *Lopez*, 514 U.S. at 560. The Court further explained that Section 922(q) is not "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Id.* at 561; see *United States* v. *Morrison*, 529 U.S. 598, 610 (2000).

2. The Ninth Circuit held in this case that *Wickard* has no application to the intrastate cultivation, possession, and distribution without charge of marijuana for purported medical purposes because, in the court of appeals' view, that class of activities neither involves economic activity nor substantially affects interstate commerce. App. 11a-12a, 16a-17a. That conclusion is fundamentally flawed. Regulation of intrastate possession, manufacture, and distribution of any controlled substance, including marijuana, is an integral and essential part of Congress's *comprehensive* regulation of the interstate possession, manufacture, and distribution of such substances generally, which unquestionably

take place in large part *in* interstate commerce and categorically *affects* interstate commerce.

Congress could reasonably determine that regulation of intrastate possession, manufacture, and distribution of all controlled substances, including marijuana, is a necessary and proper measure to ensure the effectuation of its comprehensive system of regulation, which falls squarely within Congress's power under the Commerce Clause. U.S. Const. Art. I, § 8, Cl. 18; see, *e.g.*, *Jinks* v. *Richland County*, 538 U.S. 456, 461-464 (2003). As the Fourth Circuit has explained:

> Like the production of home-grown wheat, the manufacture of marijuana for personal use is an economic activity in a general sense. Further, such manufacture is prohibited pursuant to a comprehensive statutory scheme bearing on all aspects of the illegal-drug trade, which is assuredly both commercial and interstate. Thus, like the regulation of home-grown wheat, the prohibition of home-grown marijuana is 'an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated.'

Brzonkala v. *Virginia Polytechnic Inst. & State Univ.*, 169 F.3d 820, 836 n.7 (1999) (internal citation omitted) (quoting *Lopez*, 514 U.S. at 561), aff'd *sub nom. United States* v. *Morrison*, 529 U.S. 598 (2000); accord *United States* v. *Lopez*, 2 F.3d 1342, 1367 n.51 (5th Cir. 1993) ("The [CSA's] possession proscription [is] a necessary means to regulate the interstate commercial trafficking in narcotics."), aff'd, 514 U.S. 549 (1995).

a. Marijuana is a commodity that is readily purchased and sold in a well-defined market of drug trafficking. "U.S. marijuana users spent approximately

$10.5 billion on marijuana in 2000." Executive Office of the President, Office of Nat'l Drug Control Policy, *Marijuana Fact Sheet*, 5 (Feb. 2004); see National Drug Intelligence Center, *National Drug Threat Assessment 2003* 3 (Jan. 2003) ("Marijuana is the most widely available illicit drug in the United States. * * * Prices are relatively stable, although they do range considerably from market to market."); *Illicit Drug Prices July 2003-December 2003*, Narcotics Digest Weekly, Dec. 16, 2003, at 1 & Table 4, at 19-25 (listing, for all 50 States and District of Columbia, wholesale, mid-level, and retail prices for BC Bud, commercial grade, domestic, hydroponic, locally produced, imported, Mexico-produced, and sinsemilla marijuana). The Ninth Circuit accordingly erred in seizing on the fact that respondents' activities involve the production, possession, and free distribution of marijuana that is not intended to enter the stream of commerce. App. 11a, 14a n.3. The salient point is that those activities are part of the overall class of activities regulated by Congress under the CSA—the manufacture, possession, and distribution of controlled substances—that involves economic activity and substantially affects commerce. Accordingly, an assertedly "trivial" impact of an "individual instance" regulated by the statute is of "no consequence." *Maryland* v. *Wirtz*, 392 U.S. at 197.

Congress reasonably viewed intrastate drug activity, including possession and manufacture, as significantly affecting the overall interstate market of drug trafficking. Significantly, Congress found that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances"; that "after manufacture, many controlled substances are transported in interstate commerce"; that "controlled substances distributed locally usually

have been transported in interstate commerce immediately before their distribution"; and that "controlled substances possessed commonly flow through interstate commerce immediately prior to such possession." 21 U.S.C. 801(3) and (4).

Those findings comport with common sense. Local manufacturing, possession, and use of controlled substances increase the demand for such drugs, which in turn leads to increased supply and marketing to users. The manufacturing and use of controlled substances also pose an appreciable risk of diversion to others for further drug use or distribution, a result that leads to more swelling of the illicit market. Congress's unquestionable power to eradicate drug trafficking and distribution also includes the power to ban the production, possession, and use that feeds the illicit drug market. As the Ninth Circuit itself has explained: "Laws criminalizing the possession of a good decrease the demand for that good. This decreased demand results in a decrease of supply as production becomes less profitable and therefore less attractive." *United States* v. *Adams*, 343 F.3d 1024, 1033 (9th Cir. 2003), petition for cert. pending, No. 03-9072 (filed Feb. 17, 2004).[3]

Similarly, Congress rationally applied the CSA to all drug activity because it may be impossible to ascertain in any given case whether a drug, including marijuana, has either been purchased or is intended to be offered for sale. Similarly, Congress specifically found that, given the fungible nature of marijuana and drugs

[3] Local illicit drug use for purported medicinal purposes also may induce the user to refrain from consuming lawful drugs, App. 34a-35a, 36a (Beam, J., dissenting), and similarly could decrease the incentives for research and development into new legitimate drugs.

generally, "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate," especially "in terms of controls" of such substances. 21 U.S.C. 801(5).

b. The intrastate manufacture, possession, and free distribution of marijuana for purported medical purposes also significantly interferes with the CSA's purpose to establish a national, comprehensive, uniform —and closed—statutory scheme to prevent the abuse and diversion of controlled substances. The CSA is designed to "significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." H.R. Rep. No. 1444, *supra*, at 6; see *Moore*, 423 U.S. at 135 (describing CSA's purpose to guard against the "diversion of drugs from legitimate channels to illegitimate channels").

In furtherance of that central purpose, the CSA thus controls *all* manufacturing, possession, and distribution of any scheduled drug. That is why marijuana, like all other listed drugs, is a "controlled" substance under the CSA. The CSA thus "provides for control * * * of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H.R. Rep. No. 1444, *supra*, at 3. That goal cannot be achieved if the intrastate manufacturing, possession, and distribution of a drug may occur without any federal regulation. Indeed, Congress included in the CSA the specific finding that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic." 21 U.S.C. 801(6).

The adverse effect of the court of appeals' decision on the administration and enforcement of the CSA is easily illustrated as applied to the manufacture, possession, and free distribution of drugs listed in schedules II through V (such as cocaine, methadone, codeine and opium), which may be dispensed and prescribed for medical use. 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B). Although such drugs (unlike marijuana and other schedule I substances) have an accepted medical use in treatment, the CSA requires physicians, manufacturers, pharmacies, and other legitimate handlers of such drugs to comply with stringent statutory and regulatory provisions that mandate registration with the DEA, require compliance with specific production quotas, establish security controls to guard against the theft or diversion of drugs, impose recordkeeping and reporting obligations, and permit the drug to be distributed and dispensed only pursuant to specific order-form and prescription requirements. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306.

Were Congress to lack the power under the Commerce Clause to apply the CSA to the intrastate manufacture, possession, and free distribution of controlled substances on schedules II through V, persons operating intrastate could function essentially as unregulated and unsupervised drug manufacturers and pharmacies without being subject to *any* of the federal controls under the CSA. That regime would substantially undermine the CSA's purposes to establish a comprehensive and unified approach to "dangerous drug control" and to guard against the risks of drug abuse and the diversion of controlled substances from

"legitimate channels into the illicit market." H.R. Rep. No. 1444, *supra*, at 6.

Ironically, the Ninth Circuit's decision undermines the CSA to an even greater degree because it prohibits federal regulation of marijuana, a schedule I drug (like LSD and heroin), that Congress has determined has *no* accepted medical use and may not be manufactured, possessed, or distributed under *any* circumstances other than a strictly controlled research project. 21 U.S.C. 812(b), 823(f). Thus, for schedule I substances, the comprehensive statutory regime Congress has put in place is even more tightly closed than it is for substances in schedules II through V.

c. For purposes of defining Congress's power under the Commerce Clause, there is no basis for distinguishing drug activity for purported medicinal purposes and that same activity for recreational or any other purpose. The court of appeals thus critically erred in relying on the fact that respondents' activities are for purported medical purposes and that Congress's findings in 21 U.S.C. 801 do not specifically address the use of marijuana for purported medical purposes. App. 11a, 19a. The court was of the view that "concern regarding users' health and safety is significantly different in the medicinal marijuana context, where the use is pursuant to a physician's recommendation," *id.* at 11a, and that "the limited medicinal use of marijuana as recommended by a physician arguably does not raise the same policy concerns regarding the spread of drug abuse." *Ibid.* Congress has rejected those very propositions. The CSA specifies that marijuana, as a schedule I drug, has "no currently accepted medical use in treatment in the United States," a "high potential for abuse," and "a lack of accepted safety for use * * *

under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C).[4]

Moreover, even for those controlled drugs that (unlike marijuana) have been determined to have an accepted medical use in treatment and therefore are on one of the other schedules, the CSA imposes comprehensive restrictions on the manufacture, distribution, and possession of the drugs—including restrictions on the activities of physicians and pharmacies—in order to maintain the closed system of distribution and to protect the public health and safety. The court of appeals' conclusion that the manufacture, possession and free distribution for purported personal "medicinal" use justify excluding those activities altogether from the reach of the CSA is flatly inconsistent with the fundamental premises and purposes of the CSA.

---

[4] The CSA contains provisions under which a controlled substance that has been placed in schedule I (or any other schedule) may be transferred to another schedule or entirely removed from the schedules. 21 U.S.C. 811. In 2001, DEA denied a petition to reschedule marijuana, based on an evaluation of the medical and scientific evidence demonstrating that marijuana continues to meet the criteria for placement in schedule I. 66 Fed. Reg. at 20,038. The DEA relied in significant part on the medical and scientific analysis by the FDA, as well as the FDA's conclusions that "[t]here are no FDA-approved marijuana products" and "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition." *Id.* at 20,051, 20,052. The DEA previously had rejected a petition to reschedule marijuana in 1992 (57 Fed. Reg. 10,499), and that denial was affirmed by the D.C. Circuit. *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (1994) ("[T]he Administrator's findings are supported by substantial evidence," including the "testimony of numerous experts that marijuana's medicinal value has never been proven in sound scientific studies.").

The court of appeals' reliance on the purported medical purposes of respondents' drug activities also is inconsistent with this Court's decision in *Oakland Cannabis*. In holding that the CSA forecloses a medical necessity defense to an enforcement action under the CSA, the Court explained that the CSA

> reflects a determination that marijuana has no medical benefits worthy of an exception (outside the confines of a Government-approved research project). Whereas some other drugs can be dispensed and prescribed for medical use, see 21 U.S.C. § 829, the same is not true for marijuana. Indeed, for purposes of the Controlled Substances Act, marijuana has "no currently accepted medical use" at all.

532 U.S. at 491. The Court emphasized that, "[l]est there be any confusion, we clarify that nothing in our analysis, or the statute, suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act." *Id.* at 494 n.7. In short, the Ninth Circuit has constitutionalized under the Commerce Clause the very medical necessity defense that was rejected in *Oakland Cannabis*.

3. The court of appeals' decision also conflicts with the decisions of other court of appeals that have upheld the constitutionality of the CSA as applied to the manufacture and simple possession of a controlled substance. In *Proyect* v. *United States*, 101 F.3d 11 (1996), the Second Circuit sustained against a Commerce Clause challenge the conviction of a defendant who grew marijuana plants on his property. The court of appeals rejected the defendant's contention that the class of activities to be examined for an effect on interstate commerce was the production of marijuana

"only for personal consumption" and "*without intent to distribute in commerce*." *Id.* at 12, 14. The Second Circuit instead held that "[t]he nexus to interstate commerce * * * is determined by the class of activities regulated by the statute *as a whole*, not by the simple act for which an individual defendant is convicted." *Id.* at 13. The court also explained that "the class of regulated activities, even if narrowly defined as the manufacture of controlled substances, undoubtedly has a substantial impact on interstate commerce," and "[t]he fact that certain intrastate activities within this class, such as growing marijuana solely for personal consumption, may not actually have a significant effect on interstate commerce is therefore irrelevant." *Id.* at 13-14.

Similarly, in *United States* v. *Leshuk*, 65 F.3d 1105, 1112 (1995), the Fourth Circuit held that the CSA may be constitutionally applied to the "possession and cultivation" of marijuana for "personal use" that "did not substantially affect interstate commerce." The court reasoned that "*Lopez* expressly reaffirmed the principle that 'where a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of individual instances arising under that statute is of no consequence.'" *Ibid.* (quoting *Lopez*, 514 U.S. at 558). Likewise, the Eighth Circuit in *United States* v. *Davis*, 288 F.3d 359, cert. denied, 537 U.S. 882 (2002), sustained against a Commerce Clause challenge the conviction of a defendant who engaged in the wholly intrastate manufacture of homemade methamphetamine. The court of appeals looked to the class of activities regulated by the CSA as a whole and relied on the extensive findings by Congress that "demonstrate that local manufacture and distribution of controlled sub-

stances substantially affect interstate traffic in those substances." 288 F.3d at 362.

The Ninth Circuit's decision cannot be reconciled with those decisions of other courts of appeals. App. 35a-36a (Beam, J., dissenting). The Ninth Circuit narrowly defined the relevant class of activities in question to include only the intrastate production, possession, and free distribution of marijuana that is intended for personal consumption and not sale (*id.* at 11a-12a, 16a-17a), without regard to the fact that the CSA comprehensively controls specified *substances* and creates a closed system of manufacture, distribution and possession of those substances. It therefore reasonably applies comprehensively to all instances of activity involving those substances. Such regulation is permissible under the Commerce Clause because that activity as a class is either in or substantially affects commerce and because regulation of its intrastate aspects is necessary and proper to effectuate the regulatory scheme.

B. THE COURT OF APPEALS' DECISION WARRANTS THIS COURT'S REVIEW BECAUSE IT CONFLICTS WITH DECISIONS OF OTHER COURTS, PARTIALLY INVALIDATES AN ACT OF CONGRESS, AND SUBSTANTIALLY UNDERMINES THE GOVERNMENT'S ENFORCEMENT OF THE CONTROLLED SUBSTANCES ACT

1. The Ninth Circuit's decision warrants review by this Court. As explained above, that decision conflicts with decisions of other courts of appeals. It conflicts as well with the Court's decision in *Oakland Cannibas* in finding that the asserted medicinal purpose for smoking marijuana furnishes a basis for placing respondents' manufacture, distribution, and possession of marijuana

beyond the reach of the CSA. But in addition, for the first time since Congress's enactment of the CSA in 1970, a court of appeals has held that the CSA, as applied to the manufacture, possession, and distribution of a controlled substance, is unconstitutional under the Commerce Clause. That unprecedented holding of unconstitutionality warrants this Court's review. Although the court of appeals' decision arises in the context of a request for a preliminary injunction (App. 8a-9a), the court's ruling leaves no doubt that it held the CSA unconstitutional as applied to "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law." *Id.* at 11a; cf. *Walters* v. *National Ass'n of Radiation Survivors*, 473 U.S. 305, 317-319 (1985) (finding that a court's preliminarily enjoining of an Act of Congress on constitutional grounds constitutes a "holding" for purposes of a direct appeal statute).

2. The decision is also significant because it substantially undermines the government's ability to enforce the CSA in the nine States within the Ninth Circuit, which have a population of nearly 50 million people. U.S. Department of Commerce, *Statistical Abstract of the United States* 27 (1994). As discussed above (at 11-16), the CSA's prohibition against respondents' activities is essential to effectuate the CSA's purpose to establish a unified and closed system of controls. The court of appeals' decision not only prevents the government from enforcing the CSA with respect to the intrastate manufacture, possession, and free distribution of controlled substances for purported medical purposes; the court's decision also threatens a substantial increase in the level of prohibited drug activity in the States covered by the Ninth Circuit by

individuals purporting to engage in that activity for alleged medical purposes.

Indeed, the court of appeals' decision takes on added significance in light of the fact that a number of States in the Ninth Circuit—Alaska, California, Hawaii, Nevada, Oregon, and Washington—have enacted legislation permitting the use of marijuana for purported medicinal purposes as a matter of state law. Alaska Stat. §§ 11.71.090, 17.37.010-17.37.080 (Michie 2002); Haw. Rev. Stat. Ann. § 329-121 (Michie Supp. 2003); Nev. Rev. Stat. Ann. § 453A.005-453A.510 (Michie Supp. 2003); Or. Rev. Stat. 475.300-475.346 (2001); Wash. Rev. Code Ann. § 69.51.010-69.51.080 (West 1997).[5] Thus, unless the CSA can be constitutionally enforced with respect to that activity, persons in those States will be able to possess marijuana with impunity for purported medicinal use, even though the CSA reflects Congress's deliberate judgment that *all* instances of marijuana possession, manufacture, and distribution should be banned outside the specific confines of the Act itself.

The court of appeals' decision has already had a significant adverse impact by creating substantial confusion over whether the CSA may be constitutionally applied in a variety of contexts and by inviting defendants engaged in illegal drug activity to raise the

[5] A medical marijuana ballot measure likewise was approved by voters in Maine in November 1999 and codified as state law. Me. Rev. Stat. Ann. tit. 22, § 2383-B (West 2004). Colorado has authorized medical use of marijuana with an amendment to the state constitution. Colo. Const. Art. 18, § 14. Efforts are additionally underway, either through ballot initiatives or proposed state or local legislation, to authorize medical use of marijuana in Connecticut, the District of Columbia, Florida, Missouri, New York, Rhode Island, Vermont, Utah, and Detroit, Michigan.

decision below as a complete obstacle to prosecutions or other enforcement actions under the CSA. For example, in an appeal by a criminal defendant convicted of manufacturing marijuana in violation of 21 U.S.C. 841(a)(1), the Ninth Circuit has directed the parties to address whether the defendant's conduct "[w]as * * * of a 'commercial character' or 'not commercial.'" *United States* v. *McWilliams*, No. 03-50211, at 1 (9th Cir. Feb. 10, 2004) (Order).

Moreover, in an appeal by three cannabis clubs and their operators engaged in the *commercial* manufacture and sale of marijuana (including the club at issue in *Oakland Cannabis*, *supra*), the Ninth Circuit has directed the parties to address the relevance of the decision below to the district court's power to issue an injunction against the distribution and cultivation of marijuana by the cannabis clubs. *United States.* v. *Marin Alliance for Med. Marijuana*, No. 02-16335, *United States* v. *Oakland Cannabis Buyers' Coop.*, No. 02-16534, *United States* v. *Ukiah Cannabis Buyer's Club*, No. 02-16715, at 2 (Mar. 24, 2004) (Order). Similarly, in an appeal by a marijuana collective and its operators with 250 members seeking the return of 167 marijuana plants seized by the DEA pursuant to 21 U.S.C. 881, the Ninth Circuit has directed the parties to file briefs addressing the relevance of the decision below. *Wo/Men's Alliance for Medical Marijuana* v. *United States*, No. 03-15062, at 1 (9th cir. Mar. 24, 2004) (Order). In a related case pending before the district court, the collective and its operators have invoked the decision below in seeking reconsideration of the district court's denial of their request for a preliminary injunction against further enforcement efforts by the DEA. Plaintiff's Mot. for Reconsideration of August 28, 2003

Order, *County of Santa Cruz* v. *Ashcroft*, No. 03-CV-1802 JF (N.D. Cal.) (filed Feb. 23, 2004).[6]

3. Immediate review by this Court is warranted. Further proceedings in the lower courts are not needed to clarify the issues presented. The court of appeals' ruling leaves no factual or legal questions open on remand. Indeed, the court of appeals remanded this case to the district court "for entry of a preliminary injunction." App. 26a. Moreover, as explained above, there already is rapidly increasing litigation, both civil and criminal, that invokes the Ninth Circuit's decision in seeking similar or broader relief in various settings, and that decision creates an incentive for widespread violation of the CSA in the Ninth Circuit by persons who might claim medical reasons for manufacturing, distributing, or possessing marijuana or other controlled substances. The constitutionality of the Act of Congress prohibiting such conduct should not be left in doubt.

---

[6] Likewise, the decision below has been cited by an individual seeking to force the DEA to return 5 ounces of marijuana seized by the DEA. Don Nord's Response Opposing the Gov't Mot. to Dismiss at 10, *People of the State of Colorado* v. *Nord*, No. 04-CR-26 (D. Colo. filed Mar. 29, 2004). The court of appeals' decision has also been invoked by two churches seeking an injunction preventing the United States from enforcing the CSA with respect to their cannabis activities. Complaint (Count 6), *Religion of Jesus Church* v. *Ashcroft*, CV 04-00200HG (D. Haw. filed Mar. 24, 2004).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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No.

In the Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 03-15481

ANGEL MCCLARY RAICH; DIANE MONSON; JOHN DOE, NUMBER ONE; JOHN DOE, NUMBER TWO, PLAINTIFFS-APPELLANTS

v.

JOHN ASHCROFT, ATTORNEY GENERAL, AS UNITED STATES ATTORNEY GENERAL; ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS-APPELLEES

Argued and Submitted Oct. 7, 2003
Filed Dec. 16, 2003

OPINION

PREGERSON, Circuit Judge:

Two of the appellants, Angel McClary Raich and Diane Monson, are seriously ill Californians who use marijuana for medical purposes on the recommendation of their doctors. Such use is legal under California's Compassionate Use Act. Monson grows her own medical marijuana. The remaining two appellants, John Doe Number One and John Doe Number Two, assist Raich in growing her marijuana. On October 9, 2002, the appellants filed suit against John Ashcroft, the

Attorney General of the United States, and Asa Hutchinson, the Administrator of the Drug Enforcement Administration, seeking injunctive and declaratory relief based on the alleged unconstitutionality of the federal Controlled Substances Act. The appellants also seek a declaration that the medical necessity defense precludes enforcement of that act against them.

On March 5, 2003, the district court denied the appellants' motion for a preliminary injunction because the appellants had not established a sufficient likelihood of success on the merits. That ruling is now before us.

FACTUAL AND PROCEDURAL HISTORY

A. *Statutory Scheme*

1. *The Controlled Substances Act*

Congress enacted the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, ("CSA") as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513, 84 Stat. 1236. The CSA establishes five "schedules" of certain drugs and other substances and designates these items "controlled substances." 21 U.S.C. §§ 802(6), 812(a). Marijuana is a schedule I controlled substance. *Id.* § 812(c). For a drug or other substance to be designated a schedule I controlled substance, it must be found (1) that the substance "has a high potential for abuse"; (2) that the substance "has no currently accepted medical use in treatment in the United States"; and (3) that there is "a lack of accepted safety for use of the drug or other substance under medical supervision." *Id.* at § 812(b)(1). The CSA sets forth procedures by which the schedules may be modified. *Id.* at § 811(a).

Among other things, the CSA makes it unlawful to knowingly or intentionally "manufacture, distribute, or

dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance," except as provided for in the statute. 21 U.S.C. § 841(a)(1). Possession of a controlled substance, except as authorized under the CSA, is also unlawful. *Id.* § 844(a).

Congress set forth certain findings and declarations in the CSA, the most relevant of which are as follows:

> (2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.
>
> . . . .
>
> (4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.
>
> (5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, is it not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.
>
> (6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

21 U.S.C. § 801.

2. *California's Compassionate Use Act of 1996*

In 1996, California voters passed Proposition 215, which is codified as the Compassionate Use Act of 1996 ("Compassionate Use Act"), Cal. Health & Safety Code § 11362.5. Among other purposes, the Compassionate Use Act is intended

> [t]o ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

Id. § 11362.5(b)(1)(A). The Compassionate Use Act is also intended "[t]o ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction." *Id.* § 11362.5(b)(1)(B). To these ends, the Compassionate Use Act exempts "a patient, or [ ] a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician" from certain other California code sections that make possession or cultivation of marijuana illegal. *Id.* § 11362.5(d).

B. *Factual Background*

Appellants Angel McClary Raich and Diane Monson (the "patient-appellants") are California citizens who currently use marijuana as a medical treatment. Appellant Raich has been diagnosed with more than ten

serious medical conditions, including an inoperable brain tumor, life-threatening weight loss, a seizure disorder, nausea, and several chronic pain disorders. Appellant Monson suffers from severe chronic back pain and constant, painful muscle spasms. Her doctor states that these symptoms are caused by a degenerative disease of the spine.

Raich has been using marijuana as a medication for over five years, every two waking hours of every day. Her doctor contends that Raich has tried essentially all other legal alternatives and all are either ineffective or result in intolerable side effects; her doctor has provided a list of thirty-five medications that fall into the latter category alone. Raich's doctor states that foregoing marijuana treatment may be fatal. Monson has been using marijuana as a medication since 1999. Monson's doctor also contends that alternative medications have been tried and are either ineffective or produce intolerable side effects. As the district court put it: "Traditional medicine has utterly failed these women. . . ."

Appellant Monson cultivates her own marijuana. Raich is unable to cultivate her own. Instead, her two caregivers, appellants John Doe Number One and John Doe Number Two, grow it for her. These caregivers provide Raich with her marijuana free of charge. They have sued anonymously in order to protect Raich's supply of medical marijuana. In growing marijuana for Raich, they allegedly use only soil, water, nutrients, growing equipment, supplies and lumber originating from or manufactured within California. Although these caregivers cultivate marijuana for Raich, she processes some of the marijuana into cannabis oils, balm, and foods.

On August 15, 2002, deputies from the Butte County Sheriff's Department and agents from the Drug Enforcement Agency ("DEA") came to Monson's home. The sheriff's deputies concluded that Monson's use of marijuana was legal under the Compassionate Use Act. However, after a three-hour standoff involving the Butte County District Attorney and the United States Attorney for the Eastern District of California, the DEA agents seized and destroyed Monson's six cannabis plants.

C. *Procedural History*

Fearing raids in the future and the prospect of being deprived of medicinal marijuana, the appellants sued the United States Attorney General John Ashcroft and the Administrator of the DEA Asa Hutchison on October 9, 2002. Their suit seeks declaratory relief and preliminary and permanent injunctive relief. They seek a declaration that the CSA is unconstitutional to the extent it purports to prevent them from possessing, obtaining, manufacturing, or providing cannabis for medical use. The appellants also seek a declaration that the doctrine of medical necessity precludes enforcement of the CSA to prevent Raich and Monson from possessing, obtaining, or manufacturing cannabis for their personal medical use.

On March 5, 2003, the district court denied the appellants' motion for a preliminary injunction. The district court found that, "despite the gravity of plaintiffs' need for medical cannabis, and despite the concrete interest of California to provide it for individuals like them," the appellants had not established the required "'irreducible minimum' of a likelihood of success on the merits under the law of this Circuit. . . ." The appellants filed a timely notice of appeal on

March 12, 2003. We have jurisdiction to hear this interlocutory appeal pursuant to 28 U.S.C. § 1292(a)(1).[1]

STANDARD OF REVIEW

A district court's order regarding preliminary injunctive relief is subject to limited review. *United States* v. *Peninsula Communications, Inc.*, 287 F.3d 832, 839 (9th Cir. 2002). The grant or denial of a preliminary injunction will be reversed only where the district court abused its discretion or based its decision on an erroneous legal standard or on clearly erroneous findings of fact. *Id.* The legal premises underlying a preliminary injunction are reviewed *de novo*. *See A &*

---

[1] As a threshold matter, the dissent questions the justiciability of this case. The dissent states that the plaintiffs "allege three instances of injury in their prayer for relief" and believes that two of these "injuries" are not ripe for review. The dissent essentially concedes, however, that based on the threat of future seizure of their plants, the plaintiffs have standing and their claims are ripe. This is all that is required for the plaintiffs to challenge the constitutionality of the CSA as applied to them. Once the plaintiffs have established standing on their claim that challenges the constitutionality of the CSA as applied to them, they are entitled to any appropriate *remedies* that necessarily follow from demonstrating the likelihood of success on that claim of unconstitutionality. The remedies sought are not properly understood as separate "injuries." All of the relief sought by the plaintiffs necessarily follows from the claim—the challenge to the constitutionality of the CSA as-applied—for which they undisputedly have standing and which is clearly ripe. This result is completely consistent with the case or controversy requirement of Article III. *See California Pro-Life Council, Inc.* v. *Getman*, 328 F.3d 1088, 1094 n.2 (9th Cir. 2003) (noting that, whether characterized as a question of standing or ripeness, "we ask whether there exists a constitutional case or controversy and whether the issues presented are definite and concrete, not hypothetical and abstract." (quotation marks omitted)).

M Records, Inc. v. *Napster, Inc.*, 284 F.3d 1091, 1096 (9th Cir. 2002); *Foti* v. *City of Menlo Park*, 146 F.3d 629, 634-35 (9th Cir. 1998) ("Although we review a district court's decision to deny a motion for a preliminary injunction for an abuse of discretion, we review the legal issues underlying the district court's decision de novo." (citations omitted)).

ANALYSIS

The traditional test for granting preliminary injunctive relief requires the applicant to demonstrate: (1) a likelihood of success on the merits; (2) a significant threat of irreparable injury; (3) that the balance of hardships favors the applicant; and (4) whether any public interest favors granting an injunction. *See Dollar Rent A Car of Wash., Inc.* v. *Travelers Indem. Co.*, 774 F.2d 1371, 1374 (9th Cir. 1985); *see also* SCHWARZER, TASHIMA & WAGSTAFFE, CAL. PRAC. GUIDE: FED. CIV. PRO. BEFORE TRIAL, ¶ 13:44 at 13-15 (The Rutter Group 2003).

Our court also uses an alternative test that requires the applicant to demonstrate either: a combination of probable success on the merits and the possibility of irreparable injury; or serious questions going to the merits and that the balance of hardships tips sharply in the applicant's favor. *See First Brands Corp.* v. *Fred Meyer, Inc.*, 809 F.2d 1378, 1381 (9th Cir. 1987). These two tests are not inconsistent. Rather, they represent a continuum of equitable discretion, whereby "the greater the relative hardship to the moving party, the less probability of success must be shown." *Nat'l Ctr. for Immigrants Rights, Inc.* v. *INS*, 743 F.2d 1365, 1369 (9th Cir. 1984).

A. *The Merits of the Appellants' Case*

Congress passed the CSA based on its authority under the Commerce Clause of the Constitution. The Commerce Clause grants Congress the power to "regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes. . . ." U.S. Const. art. I, § 8, cl. 3. The appellants argue that the Commerce Clause cannot support the exercise of federal authority over the appellants' activities. The Supreme Court expressly reserved this issue in its recent decision, *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 494 n.7, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001) ("Nor are we passing today on a constitutional question, such as whether the Controlled Substances Act exceeds Congress' power under the Commerce Clause."). We find that the appellants have demonstrated a strong likelihood of success on their claim that, as applied to them, the CSA is an unconstitutional exercise of Congress' Commerce Clause authority. We decline to reach the appellants' other arguments, which are based on the principles of federalism embodied in the Tenth Amendment, the appellants' alleged fundamental rights under the Fifth and Ninth Amendments, and the doctrine of medical necessity.

1. *Defining the Class of Activities*

The district court found that the Commerce Clause supports the application of the CSA to the appellants. Indeed, we have upheld the CSA in the face of past Commerce Clause challenges. *See United States* v. *Bramble*, 103 F.3d 1475, 1479-80 (9th Cir. 1996); *United States* v. *Tisor*, 96 F.3d 370, 375 (9th Cir. 1996); *United States* v. *Kim*, 94 F.3d 1247, 1249-50 (9th Cir. 1996); *United States* v. *Visman*, 919 F.2d 1390, 1393 (9th Cir.

1990); *United States* v. *Montes-Zarate*, 552 F.2d 1330, 1331 (9th Cir. 1977); *United States* v. *Rodriquez-Camacho*, 468 F.2d 1220, 1222 (9th Cir. 1972). But none of the cases in which the Ninth Circuit has upheld the CSA on Commerce Clause grounds involved the use, possession, or cultivation of marijuana for medical purposes.

In arguing that these cases should govern here and should foreclose the appellants' Commerce Clause challenge, the appellees correctly note that "'where *a general regulatory statute bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under that statute is of no consequence.'" *United States* v. *Lopez*, 514 U.S. 549, 558, 115 S. Ct. 1624, 131 L. Ed. 2d 626 (1995) (quoting *Maryland* v. *Wirtz*, 392 U.S. 183, 197 n.27, 88 S. Ct. 2017, 20 L. Ed. 2d 1020 (1968) (first emphasis added in *Lopez*)). In *Visman*, we upheld the CSA on Commerce Clause grounds and restated this principle: "'Where the *class of activities* is regulated and that class is within the reach of federal power, the courts have no power to excise, as trivial, individual instances of the *class*.'" 919 F.2d at 1393 (quoting *Perez* v. *United States*, 402 U.S. 146, 154, 91 S. Ct. 1357, 28 L. Ed. 2d 686 (1971)) (emphasis by *Visman*; quotation marks omitted).[2]

But here the appellants are not only claiming that their activities do not have the same effect on interstate commerce as activities in other cases where the CSA has been upheld. Rather, they contend that, whereas

[2] *Visman* upheld the application of the CSA to the intrastate criminal cultivation of marijuana plants found rooted in soil but intended for sale. *See* 919 F.2d at 1392-93.

the earlier cases concerned drug *trafficking*, the appellants' conduct constitutes a *separate and distinct class of activities*: the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law.

Clearly, the way in which the activity or class of activities is defined is critical. We find that the appellants' class of activities—the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician—is, in fact, different in kind from drug trafficking. For instance, concern regarding users' health and safety is significantly different in the medicinal marijuana context, where the use is pursuant to a physician's recommendation. Further, the limited medicinal use of marijuana as recommended by a physician arguably does not raise the same policy concerns regarding the spread of drug abuse. Moreover, this limited use is clearly distinct from the broader illicit drug market—as well as any broader commercial market for medicinal marijuana—insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce.

A narrow categorization of the appellants' activity is supported by our recent decision in *United States* v. *McCoy*, 323 F.3d 1114 (9th Cir. 2003). In *McCoy*, we held that 18 U.S.C. § 2252(a)(4)(B), a statute purportedly prohibiting the possession of child pornography, was unconstitutional as applied to intrastate possession of a visual depiction (or depictions) that has not been mailed, shipped, or transported interstate and is not intended for interstate distribution, or for any economic or commercial use, including the exchange of the

prohibited material for other prohibited material. *See McCoy*, 323 F.3d at 1115. *McCoy* involved a photograph taken at home of a mother and daughter with their genital areas exposed. *Id.* at 1115. The photograph never entered into and was never intended for interstate or foreign commerce. *Id.* at 1132. The dissent in *McCoy* argued that the majority had engaged in an impermissible as-applied analysis, that the activity fell within the language of the statute, and that the majority was attempting to excise a particular act as trivial. *See id.* at 1134, 1140-41 (Trott, J., dissenting). The majority held that the conduct at issue in *McCoy* represents a "substantial portion" of the conduct covered by the relevant statute and therefore can be considered a *separate class of activity*. *Id.* at 1132.

Under *McCoy*, the *class of activities* at issue in this case can properly be defined as the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician and in accordance with state law. This class of activities does not involve sale, exchange, or distribution. As was the case in *McCoy*, the class of activities here represents a substantial portion of the conduct covered by the statute—at the time of the motion for a preliminary injunction, Alaska, Arizona, California, Colorado, Hawaii, Maine, Nevada, Oregon, and Washington had passed laws permitting cultivation and use of marijuana for medical purposes. *See McCoy*, 323 F.3d at 1132 ("This class of activity represents a substantial portion of the conduct covered by [the statute].").

2. *Substantial Effect on Interstate Commerce*

We must now answer the question whether this class of activities has an effect on interstate commerce sufficient to make it subject to federal regulation under

the Commerce Clause. *See Visman*, 919 F.2d at 1392 ("In *Perez* . . . the Court ruled that the defendants' local, illegal activity of loan sharking was within a 'class of activity' that adversely affected interstate commerce and Congress had the power to regulate it."). In two recent Commerce Clause decisions, the Supreme Court has refined Commerce Clause analysis. In *Lopez*, 514 U.S. 549, 115 S. Ct. 1624, 131 L. Ed. 2d 626 (1995), the Court struck down the Gun-Free School Zones Act of 1990 as an unconstitutional exercise of power under the Commerce Clause. *Lopez* set forth three categories of activity that Congress may properly regulate under the Commerce Clause: the "use of the channels of interstate commerce"; the "instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities"; and "those activities having a substantial relation to interstate commerce, *i.e.*, those activities that substantially affect interstate commerce." 514 U.S. at 558-59, 115 S. Ct. 1624 (citations omitted). This case involves the third category of activity.

In *United States* v. *Morrison*, 529 U.S. 598, 120 S. Ct. 1740, 146 L. Ed. 2d 658 (2000), the Supreme Court clarified Commerce Clause analysis under this third category. In that case, the Court held that the Violence Against Women Act was an invalid exercise of federal power under the Commerce Clause. 529 U.S. at 627, 120 S. Ct. 1740. *Morrison* established a controlling four-factor test for determining whether a regulated activity "substantially affects" interstate commerce: (1) whether the statute regulates commerce or any sort of economic enterprise; (2) whether the statute contains any "express jurisdictional element that might limit its reach to a discrete set" of cases; (3) whether the statute

or its legislative history contains "express congressional findings" regarding the effects of the regulated activity upon interstate commerce; and (4) whether the link between the regulated activity and a substantial effect on interstate commerce is "attenuated." *Morrison*, 529 U.S. at 610-12, 120 S. Ct. 1740; *see also McCoy*, 323 F.3d at 1119. The first and the fourth factors are the most important. *McCoy*, 323 F.3d at 1119.

a. *Whether the Statute Regulates Commerce or Any Sort of Economic Enterprise*

As applied to the limited class of activities presented by this case, the CSA does not regulate commerce or any sort of economic enterprise. The cultivation, possession, and use of marijuana for medicinal purposes and not for exchange or distribution is not properly characterized as commercial or economic activity. Lacking sale, exchange or distribution, the activity does not possess the essential elements of commerce. *See* BLACK'S LAW DICTIONARY (7th ed. 1999) ("commerce": "The exchange of goods and services, esp. on a large scale involving transportation between cities, states, and nations.").[3]

On this point, the instant case is again analogous to *McCoy*. The *McCoy* court concluded "that simple intrastate possession is not, by itself, either commercial or economic in nature, that a 'home-grown' picture of a child taken and maintained for personal use is not a fungible product, and that there is no economic

[3] Although the Doe appellants are providing marijuana to Raich, there is no "exchange" sufficient to make such activity commercial in character. As Raich states in her declaration: "My caregivers grow my medicine specifically for me. They do not charge me, nor do we trade anything. They grow my medicine and give it to me free of charge."

connection—supply and demand or otherwise—between possession of such a picture and the national multi-million dollar commercial pornography industry." *Id.* at 1131.

As the photograph in *McCoy* stood in contrast to the commercial nature of the larger child pornography industry, so does the medicinal marijuana use at issue in this case stand in contrast to the larger illicit drug trafficking industry. And it is the commercial nature of drug trafficking activities that has formed the basis of prior Ninth Circuit decisions upholding the CSA on Commerce Clause grounds. *See, e.g., Tisor*, 96 F.3d at 375 ("Intrastate *distribution* and *sale* of methamphetamine are commercial activities. The challenged laws are part of a wider regulatory scheme criminalizing interstate and intrastate *commerce* in drugs." (emphasis added)); *Kim*, 94 F.3d at 1250 ("After *Lopez*, we again acknowledged that *drug trafficking* affects interstate commerce." (emphasis added)).

The parties debate whether the "aggregation principle" of *Wickard* v. *Filburn*, 317 U.S. 111, 63 S. Ct. 82, 87 L. Ed. 122 (1942), should be employed, presumably to support a finding that the cumulative effect of the activities in this case has a commercial impact. As the regulated activity in this case is not commercial, *Wickard's* aggregation analysis is not applicable. *Morrison*, 529 U.S. at 611 n.4, 120 S. Ct. 1740 ("[I]n every case where we have sustained federal regulation under the aggregation principle in *Wickard* . . . the regulated activity was of an apparent commercial character."); *McCoy*, 323 F.3d at 1120 ("In *Lopez*, the court approved of *Wickard* 's rationale only in relation to activity the economic nature of which was obvious." (citing *Lopez*, 514 U.S. at 558, 115 S. Ct. 1624)); *United*

States v. *Ballinger*, 312 F.3d 1264, 1270 (11th Cir. 2002) ("No such aggregation of local effects is constitutionally permissible in reviewing congressional regulation of intrastate, *non-economic* activity.").[4]

The majority in *McCoy* went on to examine whether the possession of child pornography at issue in that case could fit within the *Wickard* analysis, largely because a pre-*Morrison* Third Circuit decision had done just that. *See* 323 F.3d at 1121-22. The parties pick up on this discussion and debate whether, unlike the child pornography in *McCoy*, the marijuana at issue here is "fungible" such that the aggregation principle should apply. This debate is unnecessary in light of Supreme Court precedent suggesting that the aggregation principle should only be applied where the activity's commercial character is apparent. *See Morrison*, 529 U.S. at 611 n.4, 120 S. Ct. 1740. Here it is not. Moreover, *McCoy* settled the fungibility issue less by looking at

[4] The dissent relies on *Proyect* v. *United States*, 101 F.3d 11 (2d Cir. 1996), to support the proposition that the activities at issue in this case are "essentially indistinguishable from the activity in *Wickard* . . . ." In this vein, the dissent argues that the appellants' marijuana "*could* be sold in the marketplace, and . . . is also being used for medicinal purposes in place of other drugs which would have to be purchased in the marketplace." *Proyect* is distinguishable from the instant case. Although the individual in *Proyect* argued that his activities could not be regulated under the Commerce Clause because his marijuana was allegedly for personal consumption, the case involved over 100 marijuana plants and the court found that it was "very unlikely that he personally intended to consume all of his crop. . . ." 101 F.3d at 13. Moreover, while *Proyect* argued that the marijuana was only for his personal consumption, he did not allege that it was for medicinal purposes. Therefore the class of activities involved in this case is significantly different from the class of activities involved in *Proyect*.

whether the item was one that could be freely exchanged or replaced (what one might consider to be the important characteristics of fungibility) and more by simply concluding that the photograph at issue in that case was "meant entirely for personal use, without . . . any intention of exchanging it for other items of child pornography, or using it for any other economic or commercial reasons. Nor is there any reason to believe that [Rhonda McCoy] had any interest in acquiring pornographic depictions of other children." 323 F.3d at 1122. Under these standards, the marijuana at issue in this case is similarly non-fungible, as its use is personal and the appellants do not seek to exchange it or to acquire marijuana from others in a market.

Therefore, we conclude that the first *Morrison* factor favors a finding that the CSA, as applied to the facts of this case, is unconstitutional under the Commerce Clause.[5]

[5] In a recent decision, a district court reached the opposite conclusion as to this factor. The court defined the class of activities as "intrastate cultivation and possession of marijuana for medicinal purposes. . . ." *County of Santa Cruz* v. *Ashcroft*, 279 F. Supp. 2d 1192, 1208 (N.D. Cal. 2003). The court concluded that "the declarations and findings of Congress in adopting the CSA make clear that Congress considers such activity to have a substantial effect on interstate commerce because controlled substances are fungible items that influence and contribute to a national black market for controlled substances regardless of the purposes for which they are used." *Id.* at 1209. This analysis is flawed because the congressional findings relied upon do not address the specific class of activities set forth by the court in *County of Santa Cruz*. *See id.* (citing 21 U.S.C. § 801(3)-(6)). Instead, they are concerned primarily with the trafficking and distribution of controlled substances. More importantly, the district court's analysis fails to ask the question set forth in the first *Morrison* factor: whether the statute, as applied to the particular class of activities, regulates

b. *Whether the Statute Contains Any Express Jurisdictional Element That Might Limit Its Reach*

The second factor examines whether the statute contains a "jurisdictional hook" (i.e., limitation) that would limit the reach of the statute to a discrete set of cases that substantially affect interstate commerce. *See McCoy*, 323 F.3d at 1124. No such jurisdictional hook exists in relevant portions of the CSA. *See County of Santa Cruz*, 279 F. Supp. 2d at 1209. Therefore, this factor favors a finding that Congress has exceeded its powers under the Commerce Clause.

c. *Whether the Statute or Its Legislative History Contains Express Congressional Findings Regarding the Effects of the Regulated Activity Upon Interstate Commerce*

Congress clearly made certain findings in the CSA regarding the effects of intrastate activity on interstate commerce. These findings do not specifically address the class of activities at issue here. Relevant findings include:

> (4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.
>
> (5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, is it not feasible to distinguish, in

commerce or an economic enterprise. The congressional findings do not address this question; at best, they address whether the activity—commercial or not—has some effect on interstate commerce. Finally, the district court in *County of Santa Cruz*, by looking solely to congressional findings, erroneously conflated the first and third factors.

> terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.
>
> (6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

21 U.S.C. § 801. As noted above, *supra* note 4, these findings are primarily concerned with the trafficking or distribution of controlled substances. Nevertheless, they provide some evidence that intrastate possession of controlled substances may impact interstate commerce.

Therefore, the third factor weighs in favor of finding the CSA constitutional under the Commerce Clause. But it is worth reiterating two things in this respect. First, there is no indication that Congress was considering anything like the class of activities at issue here when it made its findings. The findings are not specific to marijuana, much less intrastate medicinal use of marijuana that is not bought or sold and the use of which is based on the recommendation of a physician. Common sense indicates that the findings related to this specific class of activities would be significantly different from the findings relating to the effect of drug trafficking, generally, on interstate commerce.[6]

[6] We note that the majority in *McCoy* distinguished the CSA from the statute under consideration in that case on the basis of the fact that the CSA contains express legislative findings regarding the relationship between purely intrastate activities and interstate commerce. *McCoy*, 323 F.3d at 1128 n.24. Citing to drug trafficking cases, the majority in *McCoy* wrote: "It is pri-

Second, *Morrison* counsels courts to take congressional findings with a grain of salt.

> [T]he existence of congressional findings is not sufficient, by itself, to sustain the constitutionality of Commerce Clause legislation. As we stated in *Lopez*, [s]imply because Congress may conclude that a particular activity substantially affects interstate commerce does not necessarily make it so. Rather, [w]hether particular operations affect interstate commerce sufficiently to come under the constitutional power of Congress to regulate them is ultimately a judicial rather than a legislative question, and can be settled finally only by this Court.

Morrison, 529 U.S. at 614, 120 S. Ct. 1740 (citations and quotation marks omitted). As noted above, it is not the existence of congressional findings, but rather the first and fourth factors—whether the statute regulates commerce or any sort of economic enterprise and whether the link between the regulated activity and a substantial effect on interstate commerce is "attenuated"—that are considered the most significant in this analysis.[7] *McCoy*, 323 F.3d at 1119.

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marily on the basis of these congressional findings that we rejected Commerce Clause challenges to the [CSA]." *Id.* These statements from *McCoy* are inapposite to this case for two reasons. First, as discussed above, the drug trafficking cases—for which the congressional findings may provide adequate jurisdictional support—are different in kind from the instant case. Second, the *McCoy* majority noted that *Morrison* may affect the analysis even in those cases. *Id.* ("We express no view, however, as to the effect of *Morrison* on these cases.").

[7] The CSA's congressional findings suggest that it is impractical to distinguish between controlled substances manufactured and distributed intrastate and those manufactured and distributed

d. *Whether the Link Between the Regulated Activity and a Substantial Effect on Interstate Commerce Is "Attenuated"*

The final *Morrison* factor examines whether the link between the regulated activity and a substantial effect on interstate commerce is "attenuated." The connections in this case are, indeed, attenuated. Presumably, the intrastate cultivation, possession and use of medical marijuana on the recommendation of a physician could,

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interstate. 21 U.S.C. § 801(5) ("Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, is it not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate."). Putting aside the question of whether feasibility can provide a basis for expanding congressional powers beyond those enumerated in the Constitution, *McCoy* provides a helpful resolution of this issue as it pertains to the class of activities at issue in this case:

> Furthermore, McCoy's factual circumstances, in which she possessed a family photo for her own personal use, with no intention to distribute it in interstate or foreign commerce, do not pose a law enforcement problem of interstate commercial child pornography trafficking. While it is true that child pornography "does not customarily bear a label identifying the state in which it was produced," such problems of identification are not present in this case. As we have emphasized, McCoy's "home-grown" photograph *never entered in and was never intended for interstate or foreign commerce.*

323 F.3d at 1132 (citation omitted) (quoting *United States* v. *Kallestad*, 236 F.3d 225, 230 (5th Cir. 2000)). Applying this logic to the instant case, the feasibility of differentiating between the intrastate class of activities at issue here and more generic interstate drug trafficking is of no moment, as the marijuana in the instant case never entered into and was never intended for interstate or foreign commerce.

at the margins, have an effect on interstate commerce by reducing the demand for marijuana that is trafficked interstate. It is far from clear that such an effect would be substantial. The congressional findings provide no guidance in this respect, as they do not address the activities at issue in the present case. Although not binding, other judges that have looked at the specific question presented here have found that the connection is attenuated. As one of our colleagues wrote recently: "Medical marijuana, when grown locally for personal consumption, does not have any direct or obvious effect on interstate commerce. Federal efforts to regulate it considerably blur the distinction between what is national and what is local." *Conant* v. *Walters*, 309 F.3d 629, 647 (9th Cir. 2002) (Kozinski, J., concurring) (citation omitted). The district court in *County of Santa Cruz* also seriously questioned the strength of the link between such activities and interstate commerce. *See County of Santa Cruz*, 279 F. Supp. 2d at 1209 ("The fourth factor—whether the link between [medical marijuana use] and a substantial affect on interstate commerce is attenuated—arguably favors Plaintiffs.").[8] Therefore, we conclude that this factor

[8] At oral argument, we questioned counsel for the appellants about the origin of the marijuana seeds used by the appellants. Counsel for the appellants assured us that they came from within California. Regardless, we find that the origin of the seeds is too attenuated an issue to form the basis of congressional authority under the Commerce Clause. In *McCoy* we discussed the fact that the film and camera in that case were manufactured out of state. We expressed "substantial doubt" that this fact (which was part of the statute's jurisdictional hook in that case) "adds any substance to the Commerce Clause analysis." *McCoy*, 323 F.3d at 1125. Here, the potential out-of-state production of seeds used by the appellants for their noncommercial activity is a significantly attenuated connection between the appellants' activities and interstate commerce. If the appellees sought to premise Commerce Clause authority in this case solely on the possibility that the seeds used by the appellants traveled through interstate commerce, we would conclude, as we did in *McCoy* with respect to the out-of-state manufacture of the film and camera, that this, by itself, "provides no support for the government's assertion of federal jurisdiction." *Id.* at 1126; *see also United States* v. *Stewart*, 348 F.3d 1132, 1135 (9th Cir. 2003).

favors a finding that the CSA cannot constitutionally be applied to the class of activities at issue in this case.

On the basis of our consideration of the four factors, we find that the CSA, as applied to the appellants, is likely unconstitutional. *See McCoy*, 323 F.3d at 1124 ("It is particularly important that in the field of criminal law enforcement, where state power is preeminent, national authority be limited to those areas in which interstate commerce is truly affected. . . . The police power is, essentially, reserved to the states, *Morrison*, 529 U.S. at 618, 120 S. Ct. 1740. . . . That principle must guide our review of Congress's exercise of Commerce Clause power in the criminal law area."); *see also Morrison*, 529 U.S. at 610, 120 S. Ct. 1740 ("[A] fair reading of *Lopez* shows that the noneconomic, criminal nature of the conduct at issue was central to our decision in that case.").

Therefore, we find that the appellants have made a strong showing of the likelihood of success on the merits of their case.

B. *Hardship and Public Interest Factors*

The appellants contend that considerations of hardship and the public interest factors in this case require

entry of the requested preliminary injunction.[9] The district court found that,

> [w]hile there is a public interest in the presumption of constitutional validity of congressional legislation, and while regulation of medicine by the FDA is also important, the Court finds that these interests wane in comparison with the public interests enumerated by plaintiffs and by the harm that they would suffer if denied medical marijuana.

The district court nevertheless denied the injunction given its findings regarding the merits of the case: "[D]espite the gravity of the plaintiffs' need for medical cannabis, and despite the concrete interest of California to provide it for individuals like them, the Court is constrained from granting their request." We find that the hardship and public interest factors tip sharply in the appellants' favor.

There can be no doubt on the record as to the significant hardship that will be imposed on the patient-appellants if they are denied a preliminary injunction. The appellees do not dispute this. Instead, the appellees argue that *Oakland Cannabis Buyers' Cooperative* precludes a finding that the public interest favors the appellants. The appellees quote: "[A] court sitting in equity cannot ignore the judgment of Congress, deliberately expressed in legislation." *Oakland Cannabis Buyers' Coop.*, 532 U.S. at 497, 121 S. Ct. 1711 (quotation marks omitted). However, the relevant portion of that case dealt with what factors a district court may consider when fashioning injunctive relief. *See id.* at

[9] The district court analyzed "the issue of irreparable harm, the balance of hardships, [and] the impact of an injunction upon the public interest" all under the heading "Public Interest Factors."

495-98, 121 S. Ct. 1711. It did not address the constitutional challenges at issue here that call the very foundation of the CSA into question as applied to the class of activities at issue in this case. Therefore, the Court's admonitions[10] are not relevant to this case. It would be absurd for the Court to have meant that, no matter how strong the showing of unconstitutionality, the statute must be enforced.

The appellees also contend that granting the appellants' requested injunction would create a slippery slope as other plaintiffs seeking use of other schedule I controlled substances would bypass the statutory process established by Congress. The appellees claim that the appellants' proposed injunction therefore has the potential to significantly undermine the FDA drug approval process. Our holding is sufficiently narrow to avoid such concerns. Moreover, there is nothing contrary to the public interest in allowing individuals to seek relief from a statute that is likely unconstitutional as applied to them. The public interest of the state of California and its voters in the viability of the Compassionate Use Act also weighs against the appellees' concerns. *Cf. New State Ice Co.* v. *Liebmann*, 285 U.S. 262, 311, 52 S. Ct. 371, 76 L. Ed. 747 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its

[10] These admonitions include: "A district court cannot, for example, override Congress' policy choice, articulated in a statute, as to what behavior should be prohibited." 532 U.S. at 497, 121 S. Ct. 1711; and "Their choice (unless there is statutory language to the contrary) is simply whether a particular means of enforcing the statute should be chosen over another permissible means; their choice is not whether enforcement is preferable to no enforcement at all." *Id.* at 497-98, 121 S. Ct. 1711.

citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."). Finally, the appellees' speculative slippery slope concern is weak in comparison to the real medical emergency facing the patient-appellants in this case.

CONCLUSION

For the reasons discussed above, we reverse the district court. We find that the appellants have demonstrated a strong likelihood of success on the merits. This conclusion, coupled with public interest considerations and the burden faced by the appellants if, contrary to California law, they are denied access to medicinal marijuana, warrants the entry of a preliminary injunction. We remand to the district court for entry of a preliminary injunction consistent with this opinion.

REVERSED AND REMANDED.

BEAM, Circuit Judge, dissenting.

It is simply impossible to distinguish the relevant conduct surrounding the cultivation and use of the marijuana crop at issue in this case from the cultivation and use of the wheat crop that affected interstate commerce in *Wickard* v. *Filburn*, 317 U.S. 111, 63 S. Ct. 82, 87 L. Ed. 122 (1942). Accordingly, I dissent.

I.

At the outset, I note a justiciability problem that has not been addressed by the parties, the district court or the opinion of the panel majority. Although plaintiffs assert an "as applied" challenge to the workings of the Controlled Substances Act (CSA), the pleadings and evidentiary showings do not disclose, except with one possible exception, that the CSA has actually been

applied to any of plaintiffs' activities. This, of course, raises the question of whether this case is ripe for review and, in turn, whether plaintiffs have standing to bring this case before the court.

"[W]here it is impossible to know whether a party will ever be found to have violated a statute, or how, if such a violation is found, those charged with enforcing the statute will respond, any challenge to that statute is premature." *Alaska Airlines, Inc.* v. *City of Long Beach*, 951 F.2d 977, 986 (9th Cir. 1991). To satisfy Article III's standing requirements, a plaintiff must show that she has suffered a concrete and particularized injury in fact that is actual or imminent (not conjectural or hypothetical). Plaintiff must also show that the injury is fairly traceable to the challenged action of the defendant and that it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *Citizens for Better Forestry* v. *United States Dep't of Agric.*, 341 F.3d 961, 969 (9th Cir. 2003).

In determining whether these jurisdictional prerequisites are satisfied, a court must determine whether the plaintiff has a "a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 298, 99 S. Ct. 2301, 60 L. Ed. 2d 895 (1979). In asking for injunctive relief, plaintiffs bear a special burden of showing real or immediate threat of irreparable injury when the conduct they are seeking to enjoin has not yet occurred-it is not enough to show past injury. *San Diego County Gun Rights Comm.* v. *Reno*, 98 F.3d 1121, 1126 (9th Cir. 1996). And, the mere existence of a statute which plaintiffs feel they will be

forced to violate is not sufficient to create an Article III case or controversy. *Thomas* v. *Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1139 (9th Cir. 2000) (en banc).

In *San Diego County Gun Rights*, the court considered a pre-enforcement challenge to the constitutionality of the Violent Crime Control and Law Enforcement Act. The district court had dismissed the claims for lack of standing and ripeness because none of the individual plaintiffs had been prosecuted, arrested or incarcerated for violation of the Act. The plaintiffs challenged the Act on Commerce Clause grounds,[1] and argued they had standing based on, among other things, threat of future prosecution. The court noted that in order to show an imminent and genuine threat of future prosecution, the plaintiffs must have articulated concrete plans to violate the statute. 98 F.3d at 1127. Plaintiffs can meet this prong by showing that they have in the past violated the act and intend to continue engaging in prohibited acts in the future. *Id.* (citing *Babbitt*, 442 U.S. at 303, 99 S. Ct. 2301.) Next, there must be a specific threat of prosecution, and the plaintiffs bear the burden of showing that the act in question is actually being enforced. *Id.* A specific warning of prosecution may suffice, but "a general threat of prosecution is not enough to confer standing." *Id.* Finally, the plaintiffs can meet their burden to show standing in a threat-of-prosecution situation by showing past prosecutions under the act in question. *Id.* at 1128. Because the gun rights plaintiffs could not establish the

[1] Plaintiffs also asserted claims pursuant to the Second and Ninth Amendments. The court dismissed these claims because redress of individual grievances was not cognizable under either amendment. 98 F.3d at 1125.

foregoing requirements, they did not meet their burden of showing they had Article III standing for their claim. *Id.* at 1129.

With regard to ripeness, the court noted that the issue must be "fit for judicial decision" and that "the parties will suffer hardship if we decline to consider the issues." *Id.* at 1132. Because the issues were not "purely legal" and because the plaintiffs had not been threatened with prosecution, the court found that the claims were not ripe for adjudication. *Id.*; *see also Thomas*, 220 F.3d at 1138-39 (holding that landlords who vowed not to follow an anti-discrimination housing statute did not have a justiciable claim for injunctive relief when they had not yet violated the statute and had certainly not been prosecuted for any violation).

In this case plaintiffs allege three instances of injury in their prayer for relief. They ask the court to enjoin the DEA from: 1) arresting or prosecuting them or their caregivers for possession and/or cultivation of marijuana; 2) seizing their medical cannabis; 3) seeking civil or administrative sanctions against them or their caregivers and to declare the CSA unconstitutional as applied to them through these acts. (Plaintiffs' Petition at 12-13). According to the petition, some of Monson's marijuana plants have already been seized, and past history suggests that if the DEA can find out where Raich's plants are, they will be seized as well. Thus, I concede that it is at least arguable that claim two, the "seizing" claim, may be actionable. However, applying *San Diego County Gun Rights* to the injuries alleged in claims one and three, it is clear that they are not ripe for review.

With regard to these two claims, the intent to violate the statute requirement is likely met. Plaintiffs have

violated the CSA in the past, and indicate that they will continue to do so in the future. However, plaintiffs do not show there is a threat of future prosecution or a history of past prosecutions, at least as applied to their unique factual situations. I doubt whether anyone can or will seriously argue that the DEA intends to prosecute these two seriously ill individuals. *E.g.*, Alex Kreit, Comment, *The Future of Medical Marijuana: Should the States Grow Their Own?*, 151 U. Pa. L. Rev. 1787, 1799 n.85 (2003) (noting that "DEA's limited resources make it practically impossible for its officers to enforce minor possession laws without extensive cooperation from state police").

While we can speculate on whether future prosecution is likely (given the fact that they are known users and possessors and they have not yet been arrested or prosecuted), it is the plaintiffs' burden to show standing, not this court's burden to disprove it. *Carroll* v. *Nakatani*, 342 F.3d 934, 945 (9th Cir. 2003) ("The party invoking federal jurisdiction, not the district court, bears the burden of establishing Article III standing."). Because this particular issue was not briefed or argued by the parties, or mentioned by the district court, we should remand the case to the lower court to determine whether the threat of criminal prosecution and the possible levying of civil administrative penalties are matters which are ripe for review. I suggest that such a hearing will undoubtedly reveal that plaintiffs simply use this action to seek an advance judicial ruling on government actions that may never

be applied to them or to similarly situated individuals, if any such persons presently exist in California.[2]

II.

Because the plaintiffs arguably may have standing to assert one ripe claim of future injury, the seizure claim, I address the merits of their Commerce Clause arguments. In *Wickard*, an Ohio wheat farmer (Filburn) was fined for growing excess acres of wheat on his small farm. Filburn was charged with violation of the Agricultural Adjustment Act of 1938, which was enacted to control the volume of wheat moving in foreign and interstate commerce, an effort by Congress to address, in part, surpluses, shortages and resulting extreme price variations. Filburn asserted that the Act was an unconstitutional exercise of Congress's Commerce Clause powers because it purported to regulate farm-cultivated wheat milled into flour for on-the-farm family consumption and also used for producing poultry and livestock products which were partly consumed by the Filburn family.[3] The Court rejected this argument,

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[2] I respectfully disagree with the conclusion the court reaches in footnote one of its opinion with regard to remedies available to plaintiffs, even assuming that the court's constitutional conclusions are correct. A court has no power to provide a remedy for a claim over which it has no jurisdiction. And clearly, *California Pro-Life Council, Inc.* v. *Getman*, 328 F.3d 1088 (9th Cir. 2003), provides no support for the proposition the court announces in this regard. *Id.* at 1094 n.2 (noting that the distinction between "standing" and "ripeness" label was largely immaterial). At best, under the posture of this case, the district court may enjoin seizure of plants, nothing more.

[3] It was Filburn's practice to use part of the grain from his "small acreage" of winter wheat to feed poultry and livestock on the farm, some of which products were consumed as food on the farm and also to use some of the wheat to make "flour for home

stating, "even if [the] activity be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce." *Id.* at 125, 63 S. Ct. 82. The Court then found these activities constituted a substantial economic effect. *Id.* at 128-29, 63 S. Ct. 82.

Notably, the Court stated, "[t]hat appellee's own contribution to the demand for wheat may be trivial by itself is not enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial." *Id.* at 127-28, 63 S. Ct. 82. Rationales in support of congressional regulation of how much wheat could be grown on an individual farm included: that wheat growing for whatever purpose was an important commercial enterprise in and among the various states; that wheat surplus and price fluctuations had been a significant economic problem; that several other wheat growing countries had instilled similar growing quotas and price guarantees; and that the direct and indirect consumption of wheat on the farm where it was grown was the "most variable factor in the disappearance of the wheat crop." *Id.* at 125-27, 63 S. Ct. 82.

Except for why the marijuana at issue in this case is consumed, i.e., for medicinal rather than nutritional purposes, plaintiffs' conduct is entirely indistinguishable from that of Mr. Filburn's. The Agriculture Adjustment Act reached Filburn's wheat growing activi-

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consumption." The Supreme Court deemed all of Filburn's uses to be regulable by Congress. *Wickard*, 317 U.S. at 114, 128-29, 63 S. Ct. 82.

ties, even that part of the crop grown, directly and indirectly, for family food consumed in the home on the Filburn farm. Here, under the precedent established in *Wickard*, the CSA clearly reaches plaintiffs' activities, even though they grow, or take delivery of marijuana grown by surrogates, for personal consumption as medicine in the home as permitted by California, but not federal, law.

In reaching its decision, the court defines the regulated class as "the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician." *Ante* at 1228. The *Wickard* Court could easily have defined the class of activities as "the intrastate, noncommercial cultivation of wheat for personal food purposes." Plaintiffs argue that *Wickard* is distinguishable because Filburn was engaged in the commercial activity of farming, while their activities are purely non-economic.[4]

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[4] This "non-economic" argument apparently attempts to distinguish the usage in *Wickard* from the usage allegations in this case. In *Wickard*, the 239 bushels of wheat produced from the disputed acres were deemed to have been slated for use as follows: a portion made into flour for home use, a portion sold locally as grain, a portion fed on the farm to produce poultry and livestock products with part of these products being consumed as food on the farm, and the balance kept for seed. *Wickard*, 317 U.S. at 114, 63 S. Ct. 82. However, the Supreme Court specifically focused on the regulability of the home-consumption portion of the wheat saying, "[t]he effect of [home] consumption of home-grown wheat on interstate commerce is due to the fact that it constitutes the most variable factor in the disappearance of the wheat crop." *Id.* at 127, 63 S. Ct. 82. Therefore, even though plaintiffs' usage of their marijuana crop is all personal, given *Wickard*, the plaintiffs, in their attempt to support this non-economic argument, seek to advance an immaterial factual distinction that leads to no legal difference between the two situations.

This argument fails on two fronts. The cultivation of marijuana for medicinal purposes is commercial in nature. The argument ignores the fungible, economic nature of the substance at issue-marijuana plants-for which there is a well-established and variable interstate market, albeit an illegal one under federal law. And, the growing of wheat for family consumption as flour, which was and is a legal enterprise in Ohio and other states, is as non-economic as it is possible to get with cultivated crops.

The Court in *United States* v. *Lopez*, 514 U.S. 549, 560-61, 115 S. Ct. 1624, 131 L. Ed. 2d 626 (1995) and *United States* v. *Morrison*, 529 U.S. 598, 610, 120 S. Ct. 1740, 146 L. Ed. 2d 658 (2000), expressly affirmed the continuing validity of *Wickard*. And, when put to the tests developed by *Lopez* and clarified in *Morrison*, the CSA clearly passes constitutional muster especially as applied to the plaintiffs. At the risk of some redundancy, I review each *Morrison* refinement under the allegations plaintiffs make in this case.

A. Is this particular activity economic or non-economic, but necessarily regulated as part of a larger regulatory scheme?

Even assuming that the court has correctly defined the class-"the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician"-the conduct at issue is subject to regulation. First, as earlier stated, I respectfully disagree with the court's insertion of the term "noncommercial" into the class definition because the activity at issue here is economic. Plaintiffs are growing and/or using a fungible crop which *could* be sold in the marketplace, and which is also being used for

medicinal purposes in place of other drugs which would have to be purchased in the marketplace. As also earlier indicated, this activity is essentially indistinguishable from the activity in *Wickard*, and our sister circuits have recognized the similarities. *See Proyect* v. *United States*, 101 F.3d 11, 14 (2d Cir. 1996) (per curiam) (rejecting Commerce Clause challenge to a conviction under 21 U.S.C. § 841(a)(1) for growing marijuana even though there was no evidence that the drug was intended for interstate distribution). In *Proyect*, the court noted that cultivation of marijuana for individual use *did* affect commerce in the same way that Filburn's personal consumption of wheat did:

> In any event, the cultivation of marijuana for personal consumption most likely *does* substantially affect interstate commerce. This is so because "it supplies a need of the man who grew it which would otherwise be reflected by purchases in the open market." *Wickard* v. *Filburn*, 317 U.S. 111, 128, 63 S. Ct. 82, 91, 87 L. Ed. 122 (1942). As such, there is "no doubt that Congress may properly have considered that [marijuana] consumed on the [property] where grown if wholly outside the scheme of regulation would have a substantial effect" on interstate commerce. *Id.* at 128-29, 63 S. Ct. at 90-91.

Proyect, 101 F.3d at 14 n.1.[5]

[5] At footnote four of its opinion, the court attempts to distinguish the reach of *Proyect* by noting the involvement of 100 marijuana plants. We know that six cannabis plants were seized from Monson in just one instance and that Raich regularly receives an undisclosed amount of marijuana from her purported benefactors. Over time it is likely that many times over 100 plants will be consumed by these two users alone. Thus, the distinction the

Similarly, cultivating marijuana for personal[6] use keeps plaintiffs from seeking an outside source of either marijuana, or possibly, a (federally) legally prescribed and dispensed drug such as Marinol-both of which are articles of interstate commerce. As with the wheat consumed as food by the Filburns, plaintiffs are supplying their own needs, here symptom-relieving drugs, without having to resort to the outside marketplace. This deportment obviously has an effect upon interstate commerce.

However, even if the word "non-economic" is rightly included within the court's class definition, plaintiffs' behavior is still reached if its regulation is essential to reaching the larger commercial activity. In *United States* v. *Leshuk*, 65 F.3d 1105 (4th Cir. 1995), the court held that the *Lopez* opinion did not alter its previous holding that the possession prohibitions in the CSA were a constitutional exercise of Congress's powers pursuant to the Commerce Clause. *Id.* at 1112. Further, the court noted that the act was not

> unconstitutional *as applied* if his possession and cultivation were for personal use and did not substantially affect interstate commerce. Although a conviction under the Drug Act does not require the government to show that the specific conduct at issue substantially affected interstate commerce . . . *Lopez* expressly reaffirmed the principle that

court attempts to reach is counter-productive to its arguments and actually supports the thrust of this dissent.

[6] To use a well-known basketball term, this case would be a "slam dunk" against Ms. Raich if she were paying her remote suppliers to grow the marijuana she uses. As it is, the consideration the caregivers receive is knowing that Ms. Raich is purportedly in less pain because of their efforts.

> "where a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of individual instances arising under that statute is of no consequence."

Id. (quoting *Lopez*, 514 U.S. at 558, 115 S. Ct. 1624 (quoting *Maryland* v. *Wirtz*, 392 U.S. 183, 197 n.27, 88 S. Ct. 2017, 20 L. Ed. 2d 1020 (1968))) (emphasis added). *See also Proyect*, 101 F.3d at 14 (quoting the same passage from *Lopez*); *United States* v. *Wall*, 92 F.3d 1444, 1461 (6th Cir. 1996) (Boggs, J., concurring and dissenting) (noting that noncommercial activity is subject to congressional oversight when "its regulation is an essential part of the regulation of some commercial activity").

Prior to *Lopez* and *Morrison*, this circuit held that the CSA does not violate the Commerce Clause. In *United States* v. *Visman*, 919 F.2d 1390 (9th Cir. 1990), the court found that marijuana plants "rooted in the soil" (and therefore which could not have crossed state lines) *do* affect interstate commerce. *Id.* at 1392-93. The court deferred to Congress's findings that "controlled substances have a detrimental effect on the health and general welfare of the American people and that intrastate drug activity affects interstate commerce." *Id.* at 1393. Notably, the court held that "*local* criminal cultivation of marijuana is within a class of activities that adversely affects interstate commerce." *Id.* (emphasis added).

Then, in *United States* v. *Kim*, 94 F.3d 1247, 1250 (9th Cir. 1996), this circuit affirmed the continuing validity of *Visman* in light of the *Lopez* decision. *See also United States* v. *Tisor*, 96 F.3d 370, 374 (9th Cir. 1996) (rejecting Commerce Clause challenge to the CSA after *Lopez*). Furthermore, in *United States* v.

Bramble, 103 F.3d 1475, 1479 (9th Cir. 1996), the court affirmed, with little comment, the district court's rejection of the defendant's Commerce Clause challenge in his conviction for simple possession of marijuana. The *Bramble* district court noted congressional findings that local distribution and possession of illegal drugs contribute to ever increasing interstate drug trafficking. So, even though Bramble was guilty of only simple possession, it was clearly recognized that "there is an interstate market for illegal drugs." 894 F. Supp. 1384, 1395 (D. Haw. 1995).

Of course, none of these cases involve the precise, unique facts involved in this litigation, where plaintiffs are medicinal users of marijuana, grow their own supply or obtain it free of charge from surrogate producers, and do so lawfully under state law. However, because the just-described conduct is still illegal under federal law, there is no meaningful distinction[7] between the simple possessor in *Bramble* and plaintiffs. If Congress cannot reach individual narcotic growers, possessors, and users, its overall statutory scheme will be totally undermined. The goal of the CSA is to prevent the interstate marijuana trade, even medicinal marijuana. Because plaintiffs' actions violate a federal statute, inclusion in the class formulation "for personal medical purposes on the advice of a physician" adds nothing to the analysis. While this result may seem unduly harsh since the plaintiffs are seriously ill, in the eyes of the DEA agent, there is no legal distinction between the

[7] Admittedly, one distinction is that the possessor and user in *Bramble* purchased the marijuana, presumably from a dealer. But, as admitted at oral argument, plaintiffs and their surrogates obviously purchased the *seeds* from an outside source.

simple user and possessor in *Bramble* and *Leshuk* and the plaintiffs.

That medicinal marijuana is acceptable in several states surrounding California also undermines the court's conclusion. Even if the plants are grown for purely medicinal purposes, it is probable that an interstate market for medicinal marijuana has developed with users from surrounding jurisdictions. All of this contributes to "swelling the interstate traffic in such substances." 21 U.S.C. § 801(4) (Congressional findings in support of the CSA). Thus, the activity in question here is almost certainly economic, but even if it is not, as held in *Lopez*, its regulation is essential for Congress's regulation of the larger economic activity of the drug trade.

B. Does the CSA contain a jurisdictional element?

A jurisdictional element is a specific provision in a federal statute which would require the government to establish facts "justifying the exercise of federal jurisdiction in connection with any individual application of the statute." *United States* v. *Rodia*, 194 F.3d 465, 471 (3d Cir. 1999). There is nothing in the statute at issue here which makes a connection to interstate commerce an element of the offense.

C. Were there adequate congressional findings?

As noted in *Visman*, *Kim* and *Bramble*, the congressional findings in the CSA have already been relied upon by this circuit. *See also United States* v. *Rodriquez-Camacho*, 468 F.2d 1220, 1221-22 (9th Cir. 1972). Admittedly, the findings do not address the specific use at issue here-cultivation and personal use for medicinal purposes. However, because medicinal use is not permitted by federal law, I fail to see how

this is a particularly relevant concern. Congressional findings contained in 21 U.S.C. § 801(4) specifically state that, "Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances." As pointed out above, plaintiffs' conduct does, or will, contribute to swelling the interstate traffic in marijuana, including medicinal marijuana.

D. What is the extent of the attenuation between this conduct and interstate commerce?

Finally, the court contends that circuit precedent dictates that we recognize such a degree of attenuation between the plaintiffs' conduct and interstate commerce that the connection is effectively severed. I disagree. I begin by acknowledging the dicta in the concurring opinion in *Conant* v. *Walters*-"Medical marijuana, when grown locally for personal consumption, does not have any direct or obvious effect on interstate commerce." *Conant* v. *Walters*, 309 F.3d 629, 647 (9th Cir. 2002) (Kozinski, J., concurring), cert. denied, — U.S. —, 124 S. Ct. 387, 157 L. Ed. 2d 276 (2003). On the other hand, Congress contemplated individual growers, possessors and users when it made its findings regarding the CSA. 21 U.S.C. § 801(4). And, in light of the growing interstate community of medicinal marijuana users, the attenuation is not great, even, perhaps, nonexistent. Accordingly, an evaluation of any attenuation factor favors the CSA's constitutionality.

Plaintiffs, and the court, rely extensively on this circuit's decision in *United States* v. *McCoy*, 323 F.3d 1114 (9th Cir. 2003), but the case does not bear the weight the court places on it. It is distinguishable in at

least one[8] key respect-marijuana is a cultivated, fungible commodity that has objective and readily transferable value in the marketplace, as compared with the noncommercial aspects of the home photograph taken by Ms. McCoy for her personal use. *See id.* at 1120. While it is clear that plaintiffs do not propose to sell or share their marijuana with others similarly situated (or even not similarly situated), they *could*. This is almost certainly not true of the *McCoy* family photograph.

This circuit's more recent decision in *United States* v. *Stewart*, 348 F.3d 1132, 2003 WL 22671036 (9th Cir. 2003) does not alter my conclusions. In *Stewart*, a case that I respectfully believe was wrongly decided, the court invalidated the defendant's conviction for possession of five home-assembled machine guns. The court found that 18 U.S.C. § 922(o) was an invalid exercise of Congress's commerce power as applied to a defendant who assembled parts into a machine gun by himself at home. The court held that because only the machine gun *parts* moved in interstate commerce, and because the guns were unique in that they could only have been made by the defendant himself (they were not part of a machine gun "kit," akin to a "chair from IKEA"), the activity was, according to a majority of the panel, beyond Congress's commerce power. *Id.* at *3.

Purportedly applying the *Morrison* test, the *Stewart* court found that possessing machine guns was not economic activity. The court noted that "[w]hatever its intended use, without some evidence that it will be sold or transferred-and there is none here-its relationship to

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[8] *McCoy* is also distinguishable because the issues there did not suffer from the standing and ripeness problems identified earlier. The *McCoy* defendant had been charged and convicted under the statute she was challenging "as applied."

interstate commerce is highly attenuated." *Id.* at *4. Furthermore, the overall regulation did not have an economic purpose. *Id.* This gun regulatory scenario is distinguishable[9] from that of the CSA and the plaintiffs' possession of the fungible, readily marketable economic commodity at issue here-the marijuana plants. There is nothing unique about Raich and Monson's marijuana seeds or the plants they produce, and in Raich's situation the marijuana plants were clearly "transferred" to her from her horticulturally inclined surrogates.

The *Stewart* court rejected the district court's reasoning that the activity was reachable because the parts had moved in interstate commerce, noting "[a]t some level, of course, everything we own is composed of something that once traveled in commerce." *Id.* at *2. With respect, I disagree, and a prime example of the frailty of this reasoning is Mr. Filburn's home-consumed wheat. Unless we trace the components of that wheat to an unacceptable level (and argue that the nitrogen and other nutrients taken up through the roots, the oxygen absorbed through the leaves and the water absorbed from the soil, all in furtherance of the wheat's growth process, had moved in interstate commerce), I don't believe that the commodity involved in *Wickard* was composed of any parts that had ever moved in interstate commerce.[10] Yet the grain was still deemed by the Supreme Court to be the proper subject

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[9] *Stewart* is also distinguishable for the same reason as *McCoy*, identified in the immediately preceding footnote.

[10] With further respect, and for similar reasons, I think it might come as a surprise to a mid-Nebraska cattle rancher that the baby calf born on his property and ultimately subject to numerous federal agricultural regulations was composed of parts that had moved in interstate commerce.

of congressional regulation through the commerce power. If Mr. Filburn's wheat production for home use was federally regulable, and *Wickard* v. *Filburn* remains binding precedent in this and every other circuit, as it does, plaintiffs' marijuana plants are subject to congressional regulation under the CSA.

III.

Three out of the four *Morrison* factors favor regulation, and the conduct in this case is indistinguishable from the conduct at issue in *Wickard* v. *Filburn*. Accordingly, I dissent.

APPENDIX B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C 02-4872 MJJ

ANGEL MCCLARY RAICH; DIANE MONSON; JOHN DOE, NUMBER ONE; JOHN DOE, NUMBER 2, PLAINTIFFS

v.

JOHN ASHCROFT, AS UNITED STATES ATTORNEY GENERAL, ET AL., DEFENDANTS

Mar. 4, 2003
As Modified Mar. 19, 2003

ORDER

JENKINS, District Judge.

INTRODUCTION

Before the Court is plaintiffs Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two's ("Raich," "Monson," or "Plaintiffs") motion for a preliminary injunction against Attorney General John Ashcroft ("Defendant" or "the government").[1] Plaintiffs seek to prevent the government

[1] The term "plaintiffs" shall refer to Angel McClary and Diane Monson, as their rights are at the core of the present case. The two John Does will be mentioned specifically when the analysis bears on them directly. The term "the government" denotes only the federal government. To avoid confusion, any reference to the state government of California will be made by using "California."

from enforcing against them the provisions of the Controlled Substances Act prohibiting the manufacture, distribution, or possession of marijuana. Through California's Compassionate Use Act of 1996, plaintiffs are permitted to use and cultivate marijuana for their personal medical purposes upon a doctor's recommendation. This Act excepts "medical marijuana" from the usual statutory prohibition against possession of cultivation of marijuana found elsewhere in California law. Federal law has no corollary exceptions, however, for the Controlled Substances Act ("CSA") does not recognize marijuana as having any legitimate medical purpose, and any possession or cultivation of marijuana remains illegal under this act. Plaintiffs ask the Court to enjoin defendant from applying federal law to their actions through a preliminary injunction.

According to plaintiffs, in resolving the constitutional issues raised by this motion, this Court will delineate the limits of state and federal regulatory authority regarding controlled substances, specifically marijuana, when grown locally and used for medical purposes. The government frames the issue a bit more narrowly, and it argues that the Court is bound by existing Ninth Circuit precedent to repel the constitutional challenges to the CSA mounted by plaintiffs. Because the Court finds that the weight of precedent precludes a finding of likelihood of success on the merits, plaintiffs' motion for a preliminary injunction is DENIED.

FACTUAL BACKGROUND

Plaintiffs Raich and Monson are two California citizens who currently use marijuana as a medical treatment for a variety of serious physical conditions. While Monson cultivates the cannabis she uses, Raich is unable to grow her own. Instead, her caregivers, the two John Doe plaintiffs, cultivate several varieties and provide them to her without charge. (See Plaintiffs' Memorandum of Law in Support of Motion for Preliminary Injunction ("Motion") at 5:17-22; *see also* Declaration of Angel McClary Raich in Support of Preliminary Injunction ("Raich Decl."), ¶ 48-49.) It is undisputed that both plaintiffs suffer from a number of severe medical conditions. Monson lives with serious chronic back pain, coupled with constant muscle spasms that often prove debilitating. (*See* Declaration of Diane Monson in Support of Motion for Preliminary Injunction ("Monson Decl."), ¶¶ 2, 3.) Her doctor states that these symptoms are caused by a degenerative disease of the spine. (Declaration of Dr. John Rose in Support of Motion for Preliminary Injunction ("Rose Decl."), ¶ 3.) Raich suffers from a daunting litany of more than ten serious medical conditions, many of them life-threatening. (*See* Raich Decl., ¶ 1.) Traditional medicine has utterly failed these women; none of the treatments, prescription medications, or other interventions attempted by them and their physicians has proven effective. (*See* Rose Decl., ¶ 5 (doctor for Diane Monson); see also Declaration of Frank Henry Lucido, M.D. in Support of Preliminary Injunction ("Lucido Decl."), ¶ 7 (doctor for Angel McClary Raich).) The only thing that has provided any relief from symptoms and/or improvement in their condition is medication with cannabis. (Rose Decl., ¶ 4; Lucido Decl., ¶ 6.)

With regard to Raich's marijuana, plaintiffs claim that it is cultivated using only water and nutrients originating from within California, and that it is grown exclusively with equipment, supplies, and materials manufactured within the borders of the state. (Motion at 6:10-14.) No similarly detailed statement of local pedigree is made for Monson's cannabis, but as she has grown it herself, her cultivation of marijuana is similarly local in nature. (*See id.* at 5:21.)

Although both plaintiffs fear that federal agents may raid their homes and deprive them of the marijuana they take on a daily basis, only Monson has actually experienced this. (*See* Raich Decl. ¶¶ 56-57; *see also* Monson Decl. ¶ 10.) She reports that deputies from the Butte County Sheriff's Department and agents from the DEA came to her home on August 15, 2002. (Monson Decl., ¶ 10.) While the sheriff's deputies concluded that Monson's use of cannabis was legally permissible under California's Compassionate Use Act, after a three-hour standoff, including an unsuccessful intervention by the local District Attorney with the United States Attorney for the Eastern District of California, the DEA agents seized and destroyed her six (6) marijuana plants. (*Id.*) To avoid a similar occurrence in the future, and to ensure that they will be able to continue to use cannabis as medication, plaintiffs filed suit in this Court on October 9, 2002, seeking declaratory relief and a permanent injunction. The present motion for a preliminary injunction was filed on October 30, 2002, and a hearing on the motion was held on December 17, 2002.

LEGAL STANDARD

There are various standards the Court can apply to determine whether a preliminary injunction should issue. To meet the "traditional" test, the movant must establish: (1) a strong likelihood of success on the merits; (2) that the balance of irreparable harm favors its case; and (3) that the public interest favors granting the injunction. *American Motorcyclist Ass'n* v. *Watt*, 714 F.2d 962, 965 (9th Cir. 1983). To prevail under the "alternate" test, the movant must demonstrate either a combination of probable success on the merits and the possibility of irreparable injury, or that serious questions are raised and that the balance of hardships tips sharply in its favor. *Id*; *Diamontiney* v. *Borg*, 918 F.2d 793, 795 (9th Cir. 1990). The formulations under the "alternate" test represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases. *Diamontiney*, 918 F.2d at 795. Under either formulation, however, an "irreducible minimum" is that the moving party must show a fair chance of success on the merits. *Stanley* v. *University of Southern California*, 13 F.3d 1313, 1319 (9th Cir. 1994).

ANALYSIS

Plaintiffs' central argument for likelihood of success on the merits focuses on their contention that it would be constitutionally improper to apply the CSA to individuals in their situation. In addition, they also claim that they have a valid medical necessity defense to any enforcement of the CSA against their use of medical marijuana. Plaintiffs' constitutional argument assumes three forms: (1) when applied to purely intrastate, non-commercial use of medical marijuana, the CSA represents an impermissible extension of

Congress' power to regulate interstate commerce; (2) enforcement of the CSA against medical use of marijuana is an infringement of rights reserved to the States through the Tenth Amendment; and (3) federal criminalization of medical marijuana violates fundamental rights of citizens that are protected by the Ninth Amendment.

1) Federal Prohibition of Medical Marijuana Through The Controlled Substances Act As an Impermissible Expansion of Congress' Commerce Clause Power

In the wake of the Supreme Court's decisions in *United States* v. *Lopez*, 514 U.S. 549, 115 S. Ct. 1624, 131 L. Ed. 2d 626 (1995) and *United States* v. *Morrison*, 529 U.S. 598, 120 S. Ct. 1740, 146 L. Ed. 2d 658 (2000), plaintiffs argue that application of the Controlled Substances Act to their cultivation and use of medical marijuana exceeds the legitimate reach of congressional power. As these two decisions somewhat abridged Congress' exercise of its Commerce Clause power, plaintiffs contend that the Commerce Clause does not apply to purely intrastate, non-commercial activities, such as medication through cannabis that is permitted by state law. (Motion at 6:24-7:1.) The CSA prohibits the manufacture, distribution, possession with intent to deliver, and even simple possession of marijuana, and Congress is permitted to enact such a law only under the mantle of its power to regulate interstate commerce. *See* 21 U.S.C. §§ 841(a)(1), 844(a); *see also* Motion at 7:21- 22 (citing *United States v. Kim*, 94 F.3d 1247 (9th Cir.1996)).

As the Supreme Court in *Lopez* and *Morrison* instructs, Congress' Commerce Clause power is not completely unfettered; it "is subject to outer limits."

Lopez, 514 U.S. at 557, 115 S. Ct. 1624. The limit relevant to the present case is that the regulated activity must have a "substantial relation to interstate commerce." *Id.* at 559, 115 S. Ct. 1624. Further, Congress must conclude that the activity has an economic effect, and this conclusion must be supported by sufficient findings, findings that are not the result of the type of "attenuated analysis" found problematic in *Morrison*. (Motion at 9:12-15 (quoting *Morrison*, 529 U.S. at 613, 120 S. Ct. 1740)[2].) Plaintiffs argue that the cultivation of medical marijuana, or at least the cultivation and use by plaintiffs in this case, does not substantially affect interstate commerce. (Motion at 10:26-28.) In addition, they assert that there are no congressional findings that local, wholly intrastate cultivation and use of cannabis for medical necessity have any such effect. (*Id.* at 11:11-12.)

Plaintiffs acknowledge that Congress has made findings related to the issue of controlled substances and their effect on interstate commerce, findings that are embodied in the statute itself. *See* 21 U.S.C. § 801(1-7).[3]

> (2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a detrimental effect on the health and general welfare of the American people.

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[2] The principle that regulated activities must be economic in nature is indeed found in *Morrison* at 613, 120 S. Ct. 1740, but the specific passage quoted by plaintiffs at 9:12-15 of their Motion is found on page 615 of the opinion.

[3] *See also* the voluminous Comprehensive Drug Abuse Prevention and Control Act of 1970, P.L. 91-513, reprinted in 1970 U.S.C.C.A.N. 4566.

> (3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because-
>
> (A) after manufacture, many controlled substances are transported in interstate commerce,
>
> (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and
>
> (C controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.
>
> (4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.
>
> (5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.
>
> (6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the

effective control of the interstate incidents of such traffic.

Id. at (2-6). Rather than ignore these findings, in effect, plaintiffs do two things: they challenge the validity of the findings; and they seek to carve out an exception for people who use locally cultivated medical marijuana that has not impacted interstate commerce in any way. (*See* Reply Memorandum in Support of Preliminary Injunction ("Reply") at 2-3.) Thus, plaintiffs argue that since Congress has failed to establish a nexus between the wholly intrastate, non-commercial use of medical marijuana and interstate commerce, the CSA as applied to them fails constitutional scrutiny.

However, defendant counters plaintiffs' arguments and asserts that the Ninth Circuit has repeatedly held that the Controlled Substances Act is a permissible exercise of congressional authority under the Commerce Clause.

> Relying on the Supreme Court's decision in *Lopez*, defendant argues that Congress exceeded its authority under the Commerce Clause when in enacted 21 U.S.C. § 841(a)(1). In particular, defendant contends that possession of a controlled substance is not necessarily a commercial activity that may be regulated under the Commerce Clause, § 841(a)(1) impermissibly regulates intrastate activity, and states have primary authority to define the penalties for possession of a controlled substance. We conclude that defendant's Commerce Clause argument lacks merit.

United States v. *Kim*, 94 F.3d 1247, 1249 (9th Cir. 1996).[4] The Court of Appeals has rejected challenges to the CSA by a defendant whose marijuana plants were found rooted in the soil, a purely intrastate activity. *See United States v. Visman*, 919 F.2d 1390, 1392 (9th Cir. 1990). The defendant in this case was convicted of possession with intent to distribute marijuana, manufacture of marijuana, and maintaining a place for the manufacture of marijuana. Importantly, he was convicted on the basis of plants that law enforcement agents found rooted in the ground, which, by definition, are not moving in interstate commerce.[5] The defendant argued that there is no reasonable basis to assume that these plants affect interstate commerce and that Congress exceeded its authority in regulating intrastate illegal conduct that affects interstate commerce. *See id.* The Ninth Circuit disagreed.

After considering precedent that upheld congressional regulation of intrastate drug activity under the CSA and other precedent that refused to excise individual instances from an entire class of permissibly regulated activity, the court upheld the conviction. *See id.* at 1392-93 (citing *United States* v. *Rodriquez-Camacho*, 468 F.2d 1220, 1221 (9th Cir. 1972) and *Perez* v. *United States*, 402 U.S. 146, 154, 91 S. Ct. 1357, 28 L. Ed. 2d 686 (1971), respectively). The *Visman* court

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[4] While the quotation mentions only "possession," the crime at issue in *Kim* was not simple possession, but possession with intent to deliver, as evidenced by the reference to 21 U.S.C. § 841(a)(1), and not § 844.

[5] Evidence of growing equipment and an indoor growing facility were also discovered at the defendant's house, but the focus of the opinion was only on the purely intrastate nature of plants rooted in the soil.

stated, "We defer to Congress' findings that controlled substances have a detrimental effect on the health and general welfare of the American people and that intrastate drug activity affects interstate commerce." *Id.* at 1393. Thus, the holding in *Visman*, which concerned purely intrastate drug activity, is equally applicable to plaintiffs' cultivation and use of marijuana, which allegedly is wholly intrastate as well. (*See* Motion at 6:10-14, 5:21.)

The Ninth Circuit has also specifically upheld the validity of the CSA in light of the Supreme Court decision in *Lopez*, distinguishing the CSA from the Gun-Free School Zones Act found unconstitutional in that case through the presence of congressional findings to support the CSA. *United States* v. *Tisor*, 96 F.3d 370, 374 (9th Cir. 1996). The Ninth Circuit has also endorsed the validity and adequacy of Congress' findings supporting the CSA.[6]

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[6] "Appellant urges that Congress may not constitutionally regulate the intrastate distribution of controlled substances. We disagree. Congress may regulate not only interstate commerce but also those wholly intrastate activities which it concludes have an effect upon interstate commerce. Marijuana is listed among the controlled substances in the challenged statute, and Congress has made specific findings as to the effect of intrastate activities in controlled substances on interstate commerce. 'This court will certainly not substitute its own judgment for that of Congress in such a matter unless the relation of the subject to interstate commerce and its effect are clearly nonexistent.' Such is not the case as regards controlled substances.

Congress has concluded that . . . controlled substances have a substantial and detrimental effect on the health and general welfare of the American people. [quoting 21 U.S.C. § 801(2)] Appellant urges that this assertion is inapplicable to marijuana. This is a matter, however, whose ultimate resolution lies in the legislature and not in the courts. It is sufficient that Congress have a rational basis for its findings." *United States* v. *Rodriquez-Camacho*, 468 F.2d 1220, 1221 (9th Cir. 1972) (quoting *Stafford* v. *Wallace*, 258 U.S. 495, 42 S. Ct. 397, 66 L. Ed. 735 (1922)); accord *Visman* 919 F.2d at 1390.

Plaintiffs assert that *Lopez* is not dispositive of the Commerce Clause issue raised herein because the Supreme Court has implicitly overruled the Ninth Circuit authority relied on by the government through its decision in *Morrison*. In *Morrison*, the Supreme Court rejected a provision of the Violence Against Women Act of 1994 ("VAWA") not because of a lack of congressional findings, as in *Lopez*, but rather, because of the inadequacy of those findings. *Morrison*, 529 U.S. at 614, 120 S. Ct. 1740. As importantly, plaintiffs argue that the Supreme Court's decision did not invalidate the entire VAWA, but just the portion giving victims of gender-based violence a civil remedy against their assailants. See *id.* at 613, n.5, 120 S. Ct. 1740. The Supreme Court only found Congress' findings in support of this particular section to be inadequate. Similarly, plaintiffs ask this Court to determine that the findings made by Congress in support of a particular provision of the CSA are inadequate. They charge that the findings are insufficient to support the exercise of Commerce Clause power over the wholly intrastate, non-economic possession and cultivation of marijuana for personal medical use, use that has been made legal under state law. (See Motion at 10.)

Contrary to plaintiffs' wishes, the Court is constrained from such a determination by the weight of precedent. As discussed above, the Ninth Circuit has repeatedly upheld the constitutionality of the CSA as applied to marijuana. See *Tisor*, 96 F.3d. at 374;

Rodriquez-Camacho, 468 F.2d at 1221. The Court of Appeals has confirmed the validity and adequacy of Congress' findings in support of the CSA, including its application to wholly intrastate cultivation of marijuana. *Visman*, 919 F.2d at 1392. This Court may not overrule a decision of the Ninth Circuit in the absence of an intervening Supreme Court decision that undermines the existing precedent, and both cases are closely on point.

> As a general rule, one three judge panel of this court cannot reconsider or overrule the decision of a prior panel. An exception to this rule arises when "an intervening Supreme Court decision undermines an existing precedent of the Ninth Circuit, and both cases are closely on point."

United States v. *Gay*, 967 F.2d 322, 327 (9th Cir. 1992) (citing *United States* v. *Mandel*, 914 F.2d 1215, 1220-21 (9th Cir. 1990)) (quoting *United States* v. *Lancellotti*, 761 F.2d 1363, 1366-67 (9th Cir. 1985)).[7] [8]

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[7] *United States* v. *Gay* set forth the rule for a three-judge panel of the Ninth Circuit in overruling the decision of another three-judge panel. The need for an applicable higher-court decision is even more pronounced in the case of a district court, such as this one, overruling Ninth Circuit precedent.

[8] The Court notes the similar conclusion reached by Judge Fogel in *Wo/Men's Alliance for Medical Marijuana* v. *United States*, No. 02-MC-7012 JF (N.D. Cal. 2002), a case presented to the Court and discussed at the hearing on the motion. The Court also notes that defendant has filed a number of Notices of Recent Case after the hearing date, attempting to draw the Court's attention to other decisions in this Circuit in which courts have declined to accept constitutional challenges to the CSA's application to medical cannabis. Plaintiffs have registered their objections to the timing of these notices, but the objections are moot, as the Court has not considered these cases.

While plaintiffs no doubt consider *Morrison* to be the type of an intervening Supreme Court decision required by the holding in *Gay*, and notwithstanding plaintiffs' attempt to create a factual record that would render their "as applied" attack successful under *Morrison*, the decision in *Morrison* is insufficiently on point to permit this Court to overrule the *Visman*, *Rodriquez-Camacho*, and *Tisor* line of cases. While the Supreme Court in *Morrison* provided some insight into its analysis of what congressional findings are necessary to meet the "substantially affects" test in the context of a commerce clause challenge, see *id.*, 529 U.S. at 614-18, 120 S. Ct. 1740, the case does not speak to or address the specific findings attendant to the CSA in a way that allows this Court to depart from existing Ninth Circuit precedent on this question. Therefore, this Court is not at liberty to depart from current authority holding that Congress' findings are sufficient to overcome a Commerce Clause challenge, even one involving a purely intrastate possession of a controlled substance.

In the final analysis, neither *Lopez* nor *Morrison* answer definitively the question posed to this Court: whether the Controlled Substances Act, as applied in this case, is beyond the purview of Congress' power to regulate activity under the Commerce Clause. Therefore, the Court is still bound by existing Ninth Circuit authority on this issue.[9]

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[9] Interestingly, the Supreme Court deliberately chose not to address this question in *Oakland Cannabis Club*. *See United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 494 n.7, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001) ("Nor are we passing today on a constitutional question, such as whether the Controlled Substances Act exceeds Congress' power under the Commerce

By arguing that the provisions of the CSA should not be applied to those who cultivate wholly intrastate medical marijuana that has not been circulated in commerce, plaintiffs are asking the Court to ignore valid Ninth Circuit decisions that have endorsed two of Congress' specific findings: (1) controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate; and (2) federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic, 21 U.S.C. § 801(5), (6). In the final analysis, this Court cannot undertake the resolution of this important issue as it is constrained from doing so by existing Circuit precedent—precedent which has found that the CSA passes constitutional muster.

2) The Controlled Substances Act As a Violation of the 10th Amendment

Plaintiffs correctly state that Congress' power to regulate interstate commerce, while plenary within the field, is nonetheless confined within limits. (Motion at 16:4-9). An important restriction on congressional

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Clause."). Thus, the existing Ninth Circuit cases are still binding law. Since the Supreme Court has deliberately chosen not to address the question of whether the CSA represents a constitutionally permissible exercise of Congress' Commerce Clause power, this Court must rely on the precedent provided by the Ninth Circuit.

As plaintiffs point out, Judge Kozinski, in his concurring opinion in *Conant* v. *Walters*, 309 F.3d 629 (9th Cir. 2002), raises interesting and substantial questions, albeit in the context of the First Amendment, regarding the constitutionality of the CSA. However, the concurring opinion in *Conant* is not the law of this Circuit on the important questions currently before this Court.

power is found in the Tenth Amendment, which is designed to proscribe the encroachment of the federal government into areas reserved for the States. Arguing that the Supreme Court has upheld the States' power to enact wholly intrastate measures protecting public health and to regulate professions that closely concern public health, plaintiffs assert that "under the Tenth Amendment, the wholly intrastate activity of possessing and cultivating medical cannabis pursuant to state law, is an exercise of the police power reserved to the State of California, primarily responsible for the health and safety of its citizens, a power central to the sovereignty of the States." (Motion at 17:13-16 (earlier quoting *Jacobson* v. *Massachusetts*, 197 U.S. 11, 38-39, 25 S. Ct. 358, 49 L. Ed. 643 (1905), and *Watson* v. *Maryland*, 218 U.S. 173, 176, 30 S. Ct. 644, 54 L. Ed. 987 (1910)).)

Defendant argues that since the passage of the Controlled Substances Act was a valid exercise of Congressional power under the Commerce Clause, plaintiffs' Tenth Amendment argument is overcome. The Supreme Court has held that a valid exercise of Commerce Clause authority that displaces States' exercise of their police powers or curtails the States' ability to legislate on matters they may consider important does not constitute an invasion of sovereign areas reserved to the States by the Tenth Amendment. *Hodel* v. *Virginia Surface Mining and Reclamation Ass'n, Inc.*, 452 U.S. 264, 291, 101 S. Ct. 2352, 69 L. Ed. 2d 1 (1981). The Constitution has given Congress various enumerated powers, including the power to regulate interstate commerce. If that power, surrendered to the federal government, is validly exercised, it does not infringe upon any sovereignty that has been retained by the

States. See *New York* v. *United States*, 505 U.S. 144, 156-57, 112 S. Ct. 2408, 120 L. Ed. 2d 120 (1992) ("It is in this sense that the Tenth Amendment 'states but a truism that all is retained which has not been surrendered.'") (quoting *United States* v. *Darby*, 312 U.S. 100, 124, 312 U.S. 657, 61 S. Ct. 451, 85 L. Ed. 609 (1941)).

Examples of where the Supreme Court has curtailed federal power under the Tenth Amendment are found when Congress has compelled some sort of state action. See *New York*, 505 U.S. at 166, 112 S. Ct. 2408 ("We have always understood that where Congress has the authority under the Constitution to pass laws requiring or prohibiting certain acts, it lacks the power directly to compel the States to require or prohibit those acts."); *Reno* v. *Condon*, 528 U.S. 141, 149, 120 S. Ct. 666, 145 L. Ed. 2d 587 (2000) (preventing the federal government from "commandeering" the state legislative process); *and Printz* v. *United States*, 521 U.S. 898, 925, 117 S. Ct. 2365, 138 L. Ed. 2d 914 (1997) ("[T]he federal government may not compel the States to implement, by legislation or executive action, federal regulatory programs."). This type of "commandeering" is not at issue in this case, for the federal government is not forcing California, or any other State, to take any action. The CSA regulates individual behavior, and plaintiffs are asking the Court to prevent the government from applying those regulations to their conduct. As the promulgation of the CSA was a legitimate exercise of Congressional power under the Commerce Clause, the Tenth Amendment is not implicated.

3) The Controlled Substances Act As a Violation of the Ninth Amendment

Plaintiffs argue that while the Tenth Amendment limits Congress solely to the powers enumerated by the Constitution, the Ninth Amendment prohibits an overly broad interpretation of those powers, in order to preserve individual liberties. (Motion at 18:3-11.) Plaintiffs assert that these liberties are not only those delineated in the Bill of Rights, but consist of unenumerated liberties as well. (*Id.* at 17-18.) For this reason, recognized rights such as the right to bodily integrity, the right to amelioration of pain, and the right to prolong one's life, while not listed by the Constitution, nonetheless equally enjoy its protection. (See *id.* at 19:4-9.) Plaintiffs argue that in determining what constitutes one of these unenumerated, yet fundamental rights, the courts should defer to the judgment of the people. (See *id.* at 23- 24.) "Moreover, the People of California and the State of California have expressly determined that 'seriously ill Californians have *the right* to obtain and use marijuana for medical purposes. . . .' Cal. Health & Safety Code § 11362.5(b)(1)(A) (emphasis added)." (*Id.* at 24:13-16.) When it infringes such a fundamental right, including the right of patients to use medication of a kind and quantity adequate to address their pain or prolong their lives, the federal government must provide a compelling reason. (*Id.* at 21:6-14) (citing *Washington* v. *Glucksberg*, 521 U.S. 702, 766, 117 S. Ct. 2258, 138 L. Ed. 2d 772 (1977).) Plaintiffs argue that application of the CSA deprives them of their fundamental right to use the only medication adequate to sustain them, thereby infringing their rights to bodily integrity, to ameliorate their pain, and to prolong their lives, and that the federal government has failed to

provide a sufficiently compelling justification for this deprivation.

Defendant counters by asserting that the CSA only deprives plaintiffs of the right to use lawfully a *type of treatment*, not the right to treatment itself. (See Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction ("Opp.") at 16-17.) Defendant directs the Court to *Carnohan* v. *United States*, 616 F.2d 1120 (9th Cir. 1980), in which the court found that a terminally ill cancer patient could not seek a declaratory judgment that he had the right to obtain and use laetrile, a non-approved drug for the treatment of cancer. The Court held that Constitutional rights of privacy and personal liberty did not afford the plaintiff the right "to obtain laetrile free of the lawful exercise of government police power." *Id.* at 1122. In this case, the Court also cited with approval the Tenth Circuit's decision in *Rutherford* v. *United States*, 616 F.2d 455 (10th Cir. 1980). The latter case also dealt with cancer patients' ability to obtain laetrile for treatment. The Tenth Circuit stated that:

> It is apparent in the context with which we are here concerned that the decision by the patient *whether to have a treatment or not* is a protected right, but his selection of a *particular treatment*, or at least a medication, is within the area of government interest in protecting public health.

Id. at 457 (emphasis added). While plaintiffs may vehemently disagree with the wisdom of the federal government's determination that marijuana has no medical efficacy and therefore, that federal law renders it unavailable for prescription to patients, they do not have a fundamental, constitutional right to obtain and use it for treatment. See 21 U.S.C. § 812, Schedule I(c)(10)

(placing marijuana in Schedule I); *see also* 21 U.S.C. § 812(b)(1)(B) (describing Schedule I drugs as having "no currently accepted medical use in treatment in the United States"); *and Rutherford*, 616 F.2d at 457. Therefore, Congress' outlawing of marijuana, even for medical uses, does not run afoul of the Ninth Amendment.

4) Availability of the Medical Necessity Defense

Plaintiffs' final argument rests of the defense of medical necessity. Medical necessity was raised as a defense to enforcement of federal marijuana laws in the Ninth Circuit's decision in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109 (9th Cir. 1999). While the Ninth Circuit accepted the possibility of a medical necessity defense to criminal prosecution for distribution of marijuana for medical purposes, see *id.* at 1115, the Supreme Court overruled this decision in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001) ("OCBC "). Nonetheless, plaintiffs maintain that the opinion has been preserved for those people who are not distributors of marijuana. (Motion at 25:6-7.) They rely for this proposition on the wording of Justice Stevens' concurring opinion, who states that since the issue before the Court in *OCBC* was a medical necessity defense to distribution, the reversal of the Ninth Circuit's decision dealt only with this possible offense, leaving the use of medical necessity by persons such as plaintiffs—"seriously ill patient[s] for whom there is no alternative means of avoiding starvation or extraordinary suffering"—as an open question. *OCBC*, 532

U.S. at 501, 121 S. Ct. 1711 (Stevens, J., concurring).[10] However, the language of the majority opinion in OCBC, delivered by Justice Thomas, is dispositive on this question.

> Lest there be any confusion, we clarify that nothing in our analysis, or the statute, suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act. Furthermore, the very point of our holding is that there is no medical necessity exception to the prohibitions at issue, even when the patient is "seriously ill" and lacks alternative avenues for relief.

Id. at 494, n.7, 121 S. Ct. 1711 (Thomas, J.) As there is no distinction between manufacturing and distribution, for which there is no medical necessity defense, it follows that there is no medical necessity defense for other prohibitions in the CSA, such as possession of marijuana.

The main foundation for the Supreme Court's position in *OCBC* rests upon Congress' findings that marijuana has no currently accepted medical use. *See id.* at 491, 121 S. Ct. 1711 (citing 21 U.S.C. § 811). The original placement of marijuana in Schedule I, the most restrictive schedule of the CSA, means that it was

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[10] Even if this reading of *OCBC* were correct, this would not shield John Does Number One and Two from possible prosecution. As they are caregivers who distribute marijuana, they would not be able to avail themselves of the necessity defense, unless they were considered to be a single "unit" with Raich for the purpose of criminal liability. While the Compassionate Use Act excludes caregivers as well as patients from California state law criminal liability, it is not clear how broad the protection a medical necessity defense would cast in a federal prosecution.

determined that marijuana has no current medical use for treatment in the United States, has a high potential for abuse, and has a lack of accepted safety for use under medical supervision. *Id.* (citing 21 U.S.C. § 812(b)(1)(A-C)).

> It is clear from the text of the Act that Congress has made a determination that marijuana has no medical benefits worthy of an exception. The statute expressly contemplates that many drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people," § 801(1), but it includes no exception at all for any medical use of marijuana. Unwilling to view this omission as an accident, and unable in any event to override a legislative determination manifest in a statute, we reject the Cooperative's argument [that a drug in Schedule I can be medically necessary, notwithstanding that it has "no medical use"].

Id. at 493, 121 S. Ct. 1711. Plaintiffs vigorously contest Congress' finding that medical marijuana has no medical application, and the evidence in their declarations is powerful testimony to support their position. Nonetheless, as the Supreme Court was not in a position to overturn the legislative determination that placed marijuana in Schedule I, and thus, made it unavailable for prescription to seriously ill people, much less so is this Court. The Court must also follow the dictate of the Supreme Court in its finding that there is no medical necessity defense for any of the prohibitions contained in the CSA, including even possession for medicinal use.

5) Public Interest Factors

Since the binding effect of prior decisions indicates that plaintiffs have demonstrated no likelihood of success on the merits, the Court need not address the issue of irreparable harm, the balance of hardships, or the impact of an injunction upon the public interest. *See Stanley* v. *University of Southern California*, 13 F.3d at 1319. However, the importance of this case dictates that these factors merit some brief attention.[11]

This case has a clear impact on the public interest of all Californians, and it obviously is of paramount interest to plaintiffs. The enactment of the Compassionate

[11] The Court notes the divergence of opinion regarding analysis of the public interest in the history of the *Oakland Cannabis Buyer's Cooperative* case. In *OCBC*, 190 F.3d 1109, 1114 (9th Cir. 1999), the Ninth Circuit found that Judge Breyer's failure to "expressly consider the public interest on the record" in *U.S.* v. *OCBC*, 5 F. Supp. 2d 1086 (N.D. Cal. 1998), was an abuse of discretion. However, the Supreme Court reversed the Ninth Circuit in its own *OCBC* decision, 532 U.S. 483, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001). In discussing the Ninth Circuit's decision, the Supreme Court held that the district court was not at liberty to consider "any and all factors that might relate to the public interest or the conveniences of the parties, including the medical needs of the Cooperative's patients." *Id.* at 497, 121 S. Ct. 1711. "On the contrary, a court sitting in equity cannot ignore the judgment of Congress, deliberately expressed in legislation. A district court cannot, for example, override Congress' policy choice, articulated in a statute, as to what behavior should be prohibited." *Id.* (citations omitted). The Supreme Court held that an analysis of the public interest is appropriate only in considering an injunction versus other means of enforcing a statute, "To the extent the district court considers the public interest and the conveniences of the parties, the court is limited to evaluating how such interest and conveniences are affected by the selection of an injunction over other enforcement mechanisms." *Id.* at 498, 121 S. Ct. 1711.

Use Act of 1996 manifests the express will of California voters to permit individuals with a medical need for marijuana treatment to have access to the drug, subject to a doctor's supervision. Federal enforcement of the Controlled Substances Act, plaintiffs assert, serves to thwart this will. This conflict between state and federal law is far from a purely theoretical quandary, as Monson's incident with the sheriff's deputies and the DEA amply demonstrates. Plaintiffs' list of medical conditions, and their statements that marijuana is the only medication that has proven effective to ameliorate their symptoms, provide strong evidence that plaintiffs will suffer severe harm and hardship if denied use of it.

Countering plaintiffs' argument, the government contends that the public interest and the other equities actually favor denial of the injunction. The only interests to which it points, though, are the presumption of constitutionality of congressional statutes and the potential of an injunction permitting the use of medical marijuana "to significantly undermine the FDA drug approval process." (Opp. at 24.)[12] In the government's view, Congress has opposed efforts to legalize marijuana and other Schedule I drugs without valid, scientific evidence that they are safe and effective and without the approval of the Food and Drug Administration. (*Id.* quoting Pub. L. No. 015-277, Div. F, 112 Stat. 2681, 760-61 (1998).) While there is a public interest in the presumption of constitutional validity of congressional legislation, and while regulation of medicine by the

[12] Defendant also argues that no irreparable injury to plaintiffs is possible if they are denied access to medical cannabis because they lack the right to obtain a drug that is not approved by the government for medical use. (Opp. at 22 (citing *Carnohan*, 616 F.2d at 1122, and *Rutherford*, 616 F.2d at 457).)

FDA is also important, the Court finds that these interests wane in comparison with the public interests enumerated by plaintiffs and by the harm that they would suffer if denied medical marijuana.

However, despite the gravity of plaintiffs' need for medical cannabis, and despite the concrete interest of California to provide it for individuals like them, the Court is constrained from granting their request. Plaintiffs are unable, on this record, to establish the required "irreducible minimum" of a likelihood of success on the merits under the law of this Circuit, and accordingly, the request for injunctive relief must be denied *See American Motorcyclist Ass'n* v. *Watt*, 714 F.2d at 965; *Stanley* v. *University of Southern California*, 13 F.3d at 1319. Since both the "traditional" and "alternative" tests for preliminary injunction require plaintiffs to demonstrate a likelihood of success on the merits, their failure to meet this requirement dictates that their motion for preliminary injunction must be denied under either standard. The fact that, in this Court's view, the equitable factors tip in plaintiff's favor does not alter the Court's conclusion.

CONCLUSION

All of plaintiffs' arguments in support of their position are unavailing: the weight of precedent precludes this Court from determining that Congress' findings in support of the CSA are insufficient to survive constitutional challenge; the CSA is not a violation of the Tenth Amendment or the Ninth Amendment; and plaintiffs cannot successfully mount a medical necessity defense.

Since plaintiffs are unable to establish any likelihood of success on the merits, their motion for preliminary injunction is DENIED.

IT IS SO ORDERED.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 03-15481

ANGELA MCCLARY RAICH; DIANE MONSON,ET AL.,
PLAINTIFFS-APPELLANTS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, AND WILLIAM B. SIMPKINS, ACTING ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS-APPELLEES

[Filed: Feb. 25, 2004]

ORDER

Before: PREGERSON, BEAM,[1] and PAEZ, Circuit Judges.

Judges Pregerson and Paez have voted to deny appellees petition for rehearing and rehearing en banc. Judge Beam voted to grant the petition for rehearing.

The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35(b).

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[1] Honorable C. Arlen Beam, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

The petition for rehearing and for rehearing en banc is DENIED.

APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. 02-4872 EMC

ANGEL MCCLARY RAICH, DIANE MONSON,
JOHN DOE NUMBER ONE, JOHN DOE NUMBER TWO

v.

JOHN ASHCROFT, AS UNITED STATES ATTORNEY
GENERAL, AND ASA HUTCHINSON, AS ADMINISTRATOR
OF THE DRUG ENFORCEMENT ADMINISTRATION

October 9, 2002

SUMMONS IN A CIVIL CASE

TO: (Name and address of defendant)

John Ashcroft
United States Attorney General
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530

and

Asa Hutchinson
Administrator
Drug Enforcement Administration
U.S. Department of Justice
700 Army Navy Drive
Arlington, VA 22202

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

Robert A. Raich
1970 Broadway, Suite 1200
Oakland, CA 94612

Randy E. Barnett
Boston University School of Law
Boston, MA 02215

David M. Michael
294 Page Street
San Francisco, CA 94102
United States Attorney

an answer to the complaint which is herewith served upon you, within 60 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

[SEAL OMITTED] OCT-9 2002
DATE

RICHARD W. WILKING
Clerk

SIGNATURE ILLEGIBLE
(By) Deputy Clerk

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. 02-4872 EMC

ANGEL MCCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, AND JOHN DOE NUMBER TWO, PLAINTIFFS

v.

JOHN ASHCROFT, AS UNITED STATES ATTORNEY GENERAL, AND ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS

[Filed: Oct. 9, 2002]

COMPLAINT FOR DECLARATORY RELIEF AND FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

Plaintiffs ANGEL MCCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, and JOHN DOE NUMBER TWO bring this action for declaratory, injunctive, and other relief, and on information and belief, hereby allege:

INTRODUCTION

1. The Defendants are unconstitutionally exceeding their authority by embarking on a campaign of seizing or forfeiting privately-grown wholly intrastate medical

cannabis from California patients and caregivers, arresting or prosecuting such patients and caregivers, mounting paramilitary raids against such patients and caregivers, harassing such patients and caregivers, and taking other civil or administrative actions against them. The Defendants purport to have authority for those actions under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

2. On November 5, 1996, the sovereign State of California and the People of the State of California, exercising their reserved powers and expressly retaining certain rights, duly enacted through the initiative process the Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5. The purposes of the Compassionate Use Act are "[tlo ensure that seriously ill Californians have the *right* to obtain and use marijuana for medical purposes" and "[t]o ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes . . . are not subject to criminal prosecution or sanction." Cal. Health & Safety Code § 11362.5(b)(1)(A), (B). (Emphasis added.) All of Plaintiffs' conduct is lawful under the Compassionate Use Act.

3. Defendants' actions are effectively preventing implementation of the Compassionate Use Act, thereby abrogating the powers and rights constitutionally reserved and retained by the sovereign State of California and the People of California under the Ninth and Tenth Amendments to the U.S. Constitution. Moreover, Defendants' actions are infringing on Plaintiffs' rights guaranteed by the Due Process Clause of the Fifth Amendment to the U.S. Constitution. Additionally, to the extent that Defendants purport to take their actions pursuant to an act of Congress, then such act

exceeds the powers of Congress granted under the Commerce Clause of the U.S. Constitution. Furthermore, the doctrine of Medical Necessity precludes Defendants' actions against Plaintiffs.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 2201.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 (e) and 1402(a)(1).

PARTIES

Plaintiffs

6. Plaintiff ANGEL McCLARY RAICH ("ANGEL") is a seriously ill patient who would likely be dead today were it not for her use of medical cannabis. ANGEL suffers from numerous severe debilitating medical conditions for which cannabis uniquely provides relief. ANGEL's primary care physician, and all of her numerous specialist physicians, support ANGEL's use of medical cannabis. ANGEL is a Medical Necessity patient-member of the Oakland Cannabis Buyers' Cooperative, from which she used to obtain her medicine. Because ANGEL cannot cultivate her own cannabis, she now relies on two caregivers who provide cannabis to her without charge. ANGEL resides in Oakland, California.

7. Plaintiff DIANE MONSON of Butte County, California is a patient who uses medical cannabis on her doctor's recommendation to treat Severe following a three-hour standoff in MONSON's front yard, federal agents raided her home Chronic Back Pain and Spasms. On August 15, 2002, followed her home and seized her six (6) medical cannabis plants, in defiance of an urgent

telephone plea by Butte County District Attorney Mike Ramsey to U.S. Attorney John K. Vincent imploring him to spare MONSON's medicine.

8. Plaintiff JOHN DOE NUMBER ONE, of Oakland, California, cultivates cannabis on ANGEL's behalf, which he supplies to ANGEL free of charge, without any cost or remuneration whatsoever. In order to protect ANGEL's supply of medical cannabis, JOHN DOE NUMBER ONE sues in an anonymous capacity. In the cultivation of ANGEL's medical cannabis, JOHN DOE NUMBER ONE uses only water and nutrients originating from within the borders of the State of California. Further, JOHN DOE NUMBER ONE uses exclusively growing equipment, supplies, and materials manufactured within the borders of the State of California. JOHN DOE NUMBER ONE cultivates for ANGEL medical-grade cannabis free of mold, fungus, pesticide residue, and other contaminates in the particular strains and potencies that ANGEL has found to be most effective in treating her specific medical conditions.

9. Plaintiff JOHN DOE NUMBER TWO, of Oakland, California, cultivates cannabis on ANGEL's behalf, which he supplies to ANGEL free of charge, without any cost or remuneration whatsoever. In order to protect ANGEL's supply of medical cannabis, JOHN DOE NUMBER TWO sues in an anonymous capacity. In the cultivation of ANGEL's medical cannabis, JOHN DOE NUMBER TWO uses only water and nutrients originating from within the borders of the State of California. Further, JOHN DOE NUMBER TWO uses exclusively growing equipment, supplies, and materials manufactured within the borders of the State of California. JOHN DOE NUMBER TWO cultivates for ANGEL medical-grade cannabis free of mold, fungus, pesticide

residue, and other contaminates in the particular strains and potencies that ANGEL has found to be most effective in treating her specific medical conditions.

Defendants

10. Defendant JOHN ASHCROFT is sued in his official capacity as the Attorney General of the United States of America, which is one of the sovereigns in our federal system of Dual Sovereignty.

11. Defendant ASA HUTCHINSON is sued in his official capacity as the Administrator of the Drug Enforcement Administration (DEA), an agency of the United States of America, which is one of the sovereigns in our federal system of Dual Sovereignty.

MEDICAL BACKGROUND

12. As a mother of two children, Plaintiff ANGEL opposed all illegal drug use, including the recreational use of marijuana, until the benefits of cannabis became unmistakable for the treatment of ANGEL's own medical conditions.

13. ANGEL suffers from the following, often interrelated, medical conditions: a) Life-Threatening Weight Loss, Malnutrition, Cachexia, and Starvation; b) Chronic Nausea; c) numerous Severe Chronic Pain afflictions from: Scoliosis, Temporomandibular Joint Dysfunction Syndrome (TMJ), Endometriosis, Headaches, Rotator Cuff Syndrome, and Uterine Fibroid Tumor; d) Post Traumatic Stress Disorder (P.T.S.D.); e) Non-Epileptic Seizures; f) Fibromyalgia; and g) an inoperable Brain Tumor. Moreover, ANGEL endured four years of Paralysis, which confined her to a Wheelchair; her doctors said she would never walk again, but she then discovered cannabis as the only treatment that brought her Paralysis into complete remission.

14. ANGEL's doctors now recommend that she medicate with cannabis every two hours. She medicates' by ingesting, smoking, and vaporizing cannabis. Her physicians emphatically insist that ANGEL "cannot be without this medicine" because severe Weight Loss and flare-ups of her Chronic Pain conditions would quickly develop. When ANGEL's Pain levels are elevated she is prone to having Seizures.

15. The Appendix hereto, *supra*, is a description of ANGEL's numerous complex medical conditions, and an explanation of how medical cannabis is the only effective treatment for her medical conditions. Plaintiffs reallege and incorporate by reference all paragraphs of the Appendix hereto as if set forth fully in the body herein.

16. Without access to medical cannabis, ANGEL would experience horrible pain, suffering, and death. Horrible pain suffering, and death constitute irreparable harm.

17. ANGEL requires over two and one-half ounces of cannabis per week, or in excess of eight pounds of cannabis per year, for her personal medical consumption. Angel is a member of the Oakland Cannabis Buyers' Cooperative (OCBC), and used to obtain her medicine there, but cannot now obtain her medicine from OCBC because of Defendant UNITED STATES OF AMERICA's actions against the OCBC starting in 1998. ANGEL lives in fear that her home will be raided, her medical cannabis will be seized, she or her caregivers will be arrested, or her property will be forfeited by Defendants' actions, whether or not the Defendants ever file criminal charges against her. Stress from that fear is further exacerbating ANGEL's already precarious medical conditions.

18. If Defendants were to take ANGEL into custody and deny her access to medical cannabis, she would suffer serious medical consequences within a matter of hours. Because of ANGEL's already fragile medical condition, even a raid by Defendants on ANGEL would trigger severe medical repercussions.

19. ANGEL is at particular risk ofbeing targeted by the Defendants: ANGEL has been quoted in electronic and print media locally, nationally, and internationally as a medical cannabis patient, and has defiantly stated that, faced with the alternative of an agonizing death, she would continue to use medical cannabis notwithstanding the federal war on cannabis patients. Contrary to claims by Defendant HUTCHINSON, the Defendants are engaging in a campaign of selective prosecution targeting medical cannabis patients, especially the ones who have been most outspoken publicly.

20. ANGEL is a Medical Necessity Patient. She is one (1) of only fourteen (14) members designated as being a Medical Necessity Patient by the OCBC following rigorous and meticulous evaluations by the OCBC's medical and administrative staff. As discussed more thoroughly herein, ANGEL suffers from numerous serious medical conditions. She would suffer imminent harm if she did not have access to cannabis. She needs cannabis to treat her medical conditions or their symptoms. She has no reasonable alternative to cannabis because she is violently allergic to virtually all pharmaceutical medications.

21. Plaintiff DIANE MONSON has suffered from Severe Chronic Back Pain and Spasms since 1989. She first tried medical cannabis in 1998, and uses it on the recommendation of her doctors in light of its remarkable efficacy at controlling her symptoms. MONSON's

Spasms are an extremely painful experience in their own right, comparable in intensity to an uncontrollable cramp. Medical cannabis completely eliminates her Spasms. Even with medical cannabis, MONSON still experiences discomfort, but cannabis greatly relieves her Chronic Pain. Without cannabis, her spasms would return and she would be subjected to intense pain that cannot be relieved any other way. MONSON has tried various combinations of prescription pharmaceutical medications, but they are often ineffective and they always disrupt her quality of life by interfering with her ability to function. In contrast, MONSON has found cannabis to be both effective and free of undesirable side-effects.

LEGAL BACKGROUND

The Commerce Clause

22. Wholly intrastate activity is beyond the power of Congress "to regulate Commerce . . . among the several States," U.S. Const. Art. 1, sec. 8. *See The Federalist* 42 (J. Madison) (referring to the power "to regulate between State and State"). Protecting wholly intrastate commerce from the reach of Congress is a constitutional imperative in our federal system. To the extent the Controlled Substances Act purports to grant Defendants' authority to conduct the activities complained of herein, such Act exceeds the authority granted to Congress under the Commerce Clause. Plaintiffs seek protection for conduct that has no effect whatsoever on interstate commerce; indeed, Plaintiffs' conduct is not commerce at all.

State Sovereignty as Confirmed in the Tenth Amendment

23. The Tenth Amendment confirms that the power of the Federal Government is subject to limits that may, in a given instance, reserve power to the States. Although the Constitution delegates to Congress the power over interstate commerce and other national concerns, the States are primarily responsible for the health and safety of their citizens, a power known as the "police power." Traditionally, no power is more central to the sovereignty of the States, and Congress lacks such a power. State governments have authority to enact measures reasonably necessary to protect public health. Congress cannot exercise its power over interstate commerce to interfere with a State's police power by prohibiting *wholly intrastate* conduct that the State mandates in the interest of health or safety. Respect for the sovereign States that comprise our Federal Union imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to "serve as a laboratory" in the trial of "novel social and economic experiments without risk to the rest of the country." The only doctrine preventing federal usurpation of traditionally State regulated activities is that such federal actions would violate the principles of federalism. To the extent the Controlled Substances Act purports to grant authority for Defendants to prohibit the conduct for which Plaintiffs herein seek protection, the Act exceeds Congress's constitutional authority by abrogating powers reserved to the State of California.

Fundamental Constitutional Rights Protected by The Fifth and Ninth Amendments

24. The Due Process Clause of the Fifth Amendment provides protection of unenumerated liberties against the federal government. The Ninth Amendment also provides protection under its express injunction that: "The enumeration in the Constitution of certain rights shall not be construed to deny or disparage others retained by the people." U.S. Const. Amend. IX. To receive constitutional protection, an unenumerated liberty must have roots in "our Nation's history, legal traditions, and practices." Infringements upon fundamental liberties call for heightened scrutiny of the means by which Congress exercises its enumerated powers.

25. The rights to bodily integrity, to ameliorate pain, and to prolong life are closely related. They are distinct rights or specific aspects of the famous trinity of "life, liberty, and the pursuit of happiness" in the Declaration of Independence. These rights, with deep roots in our Nation's history, legal tradition and practice, permit decisions about one's body to be made free from governmental intervention. In the absence of a compelling interest that would be furthered by such a proscription, the government cannot, consistent with the Constitution, abridge these rights of Plaintiffs, who are seriously ill patients. No such compelling governmental interest exists.

26. The right to consult with one's doctor about one's medical condition is also a fundamental right deeply rooted in our history, legal traditions, and practices. Moreover, imperatives established by the sanctity of the physician-patient relationship prevent Defen-

dants' interference with Plaintiffs' ability to act on their doctors' treatment recommendations.

27. Plaintiffs herein are entitled to heightened protection against Defendants' interference with Plaintiffs' exercise of their fundamental rights and liberty interests. The Constitution does not allow Congress to authorize Defendants to deny or disparage the activities for which Plaintiffs seek protection herein.

The Medical Necessity Doctrine

28. The law in the Ninth Circuit specifically and expressly applies the medical necessity doctrine to those suffering patients who require medical cannabis. There is a class of people with serious medical conditions; for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; who will suffer serious harm if they are denied cannabis; and for whom there is no legal alternative to cannabis for tile effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects. Although the Supreme Court has determined the doctrine is not available to a medical cannabis *distribution cooperative*, the applicability of the doctrine for seriously ill *patients* was not before the Court, and was notably preserved by the Court's concurrence in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001).

29. Plaintiffs ANGEL and MONSON are seriously ill patients for whom there is no alternative means of avoiding starvation or extraordinary suffering without the benefits of medical cannabis. The medical necessity doctrine is available to these seriously ill patients to use

and obtain medical cannabis for their own personal medical treatment.

Credible Threat of Actual Harm

30. Plaintiffs' fears of being victimized by Defendants are not merely theoretical. Defendants are continuing, indeed in the past year have escalated, their attacks on medical cannabis patients protected by State law in California and other States. Since September 11, 2001, Defendants have terrorized more than 35 Californians because of medical cannabis, including many individuals patients for merely their own personal cannabis medication—involving amounts as small as one (1) cannabis plant or one (1) ounce of medicine. During that same period, nearly half of all the federal marijuana cases filed in the Northern District of California have involved medical cannabis. In a public speech on February 12, 2002, Defendant HUTCHINSON asserted that enforcement of federal laws against medical cannabis was a "responsibility" of his agency. HUTCHINSON reiterated that sentiment in a September 30, 2002, letter to California Attorney General Bill Lockyer, claiming the DEA is "legally mandated" to enforce such laws. With particular reference to Plaintiff MONSON's six medical cannabis plants, HUTCHINSON praised their seizure, claiming such action was Defendants' "duty under Federal law". Defendants' tactics commonly involve commando-style raids against sick patients in their homes, the pointing of high-powered automatic weapons at patients, and traumatizing patients and their loved ones. The Defendants frequently target those patients who are the most outspoken critics of federal policy. Being victimized by Defendants once provides no security for patients: The Defendants have raided several patients on more than

one occasion—always seizing medical cannabis, and sometimes initiating prosecutions or forfeiture actions against patients' property. Defendants' threats to medical cannabis patients are not confined to California, but extend as well to patients in various other States that permit medical cannabis. Plaintiffs reasonably fear further victimization by Defendants if the Court does not grant the relief sought herein.

FIRST CAUSE OF ACTION

31. Plaintiffs reallege and incorporate by reference Paragraphs I through 30 as if set forth fully herein.

32. The Commerce Clause, Article 1, Section 8, of the U.S. Constitution provides that "Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes . . . ."

33. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any Plaintiff herein for intrastate noncommercial activities involving the personal medical cannabis of Plaintiffs ANGELS or MONSON would violate the Commerce Clause as applied to Plaintiffs.

SECOND CAUSE OF ACTION

34. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

35. The Fifth Amendment to the U.S. Constitution provides that "No person shall be . . . deprived of life, liberty, or property, without due process of law . . . ."

36. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any

Plaintiff herein for activities involving the personal medical cannabis of Plaintiffs ANGEL or MONSON would violate the Fifth Amendment as applied to Plaintiffs.

THIRD CAUSE OF ACTION

37. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

38. The Ninth Amendment to the U.S. Constitution provides that "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."

39. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any Plaintiff herein for activities involving the personal medical cannabis of Plaintiffs ANGEL or MONSON would violate the Ninth Amendment as applied to Plaintiffs.

FOURTH CAUSE OF ACTION

40. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

41. The Tenth Amendment to the U.S. Constitution provides that "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

42. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any Plaintiff herein for activities within the State of California involving the personal medical cannabis of Plaintiffs

ANGEL or MONSON would violate the Tenth Amendment as applied to Plaintiffs.

FIFTH CAUSE OF ACTION

43. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

44. Under the doctrine of medical necessity, individual patients who (1) suffer from a serious medical condition, (2) will suffer imminent harm without access to cannabis, (3) need cannabis for the treatment of their medical condition or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of their medical condition or symptoms associated with the medical condition because they have tried all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects, may use and obtain medical cannabis for their own personal medical treatment.

45. Plaintiff ANGEL suffers from numerous serious medical conditions, would suffer imminent harm without access to cannabis, needs cannabis for the treatment of her medical conditions and to alleviate symptoms associated with the medical conditions, and has tried all other reasonable legal alternatives to cannabis and found them to be ineffective or to result in intolerable side effects.

46. Plaintiff MONSON suffers from a serious medical condition, would suffer imminent harm without access to cannabis, needs cannabis for the treatment of her medical condition and to alleviate symptoms associated with the medical condition, and has tried all other reasonable legal alternatives to cannabis and found

them to be ineffective or to result in intolerable side effects.

47. The doctrine of medical necessity permits Plaintiffs ANGEL and MONSON to use and obtain cannabis for their personal medical treatment free from the threat of Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against them.

IRREPARABLE HARM

48. Plaintiffs have suffered and will continue to suffer irreparable harm due to Defendant's challenged actions and practices described in this Complaint.

49. Plaintiffs face, or treat, serious or life-threatening medical conditions requiring therapy with cannabis to alleviate increased suffering, illness, or death. Defendants' interference with Plaintiff patients' treatment, and the resulting increased risk of suffering, illness, and death, constitute irreparable harm.

50. Plaintiff patients have constitutional rights to obtain treatment to alleviate their suffering. Defendants' actions are creating well-founded fear by Plaintiffs that Defendants will attack Plaintiffs' persons, medicine, health, or property, thus exacerbating Plaintiff patients' already serious medical conditions and constituting irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court enter judgment as follows:

A. Issue a Preliminary Injunction during the pendency of this action and a Permanent Injunction enjoining Defendants from arresting or prosecuting

Plaintiffs, seizing their medical cannabis, forfeiting their property, or seeking civil or administrative sanctions against them for their activities with respect to any of the following:

(1) The possession of medical cannabis by Plaintiffs Angel McClary Raich and Diane Monson for their personal medical use;

(2) The ability of Plaintiff Angel McClary Raich to obtain medical cannabis from her Plaintiff caregivers, John Doe Number One and John Doe Number Two, for her personal medical use;

(3) The ability of Plaintiffs John Doe Number One and John Doe Number Two to cultivate and provide medical cannabis to Plaintiff Angel McClary Raich for her personal medical use;

(4) The processing of medical cannabis by Plaintiff Angel McClary Raich for her personal medical use; and

(5) The cultivation of medical cannabis by Plaintiff Diane Monson for her personal medical use.

B. Declare that enforcement of the Controlled Substances Act is unconstitutional to the extent it purports to prevent Plaintiffs from possessing, obtaining, manufacturing, or providing cannabis for Plaintiff patients' personal medical use.

C. Declare that the doctrine of Medical Necessity precludes enforcement of the Controlled Substances Act to the extent it purports to prevent ANGEL from possessing, obtaining, or manufacturing cannabis for her personal medical use.

D. Declare that the doctrine of Medical Necessity precludes enforcement of the Controlled Substances

Act to the extent it purports to prevent MONSON from possessing, obtaining, or manufacturing cannabis for her personal medical use.

E. Award Plaintiffs their reasonable attorneys' fees and costs.

F. Grant Plaintiffs such other and further relief as the Court deems just and proper.

Dated: October 9, 2002

Respectfully submitted,

ROBERT A. RAICH
DAVID M. MICHAEL
RANDY E. BARNETT

By: /s/ ROBERT A. RAICH
ROBERT A. RAICH
Attorneys for Plaintiffs

APPENDIX

MEDICAL CONDITIONS OF PLAINTIFF ANGEL McCLARY RAICH

51. Plaintiffs incorporate by reference all paragraphs in this Appendix as if set forth fully in the body of this document.

52. *Life-Threatening Weight Loss, Malnutrition, Cachexia, and Starvation:* ANGEL experiences great difficulty maintaining a healthy weight. ANGEL's physicians, including her gastroenterologist, are unable to diagnose the root cause of her weight problems or to prescribe an effective course of treatment. One fact, however, is clear: ANGEL literally cannot eat without a sufficiently high level of cannabis in her system. Without cnnabis, ANGEL's weight can drop precipitously and she runs the very real risk of Malnutrition and Starvation. One result of Starvation is death. Death constitutes irreparable harm.

53. *Nausea:* ANGEL experiences chronic Nausea, which makes eating and drinking difficult, and exacerbates her wasting weight loss conditions. Even the smell, sight, or taste of food can trigger the nausea, and eating can cause stomach cramps leaving ANGEL in wrenching pain. Pharmaceutical anti-nausea medications are ineffective, but cannabis is the only medicine that provides relief.

54. *Severe Chronic Pain:* Every second that she is awake, ANGEL experiences Pain from one or more of the Chronic Pain conditions from which she suffers. She suffers greatly from Pain every single day. Sleep provides meager escape from the ever one word present Pain she experiences. Her pervasive Pain and

other conditions have made ANGEL permanently disabled. The prolonged Pain and suffering from her medical conditions significantly interferes with the quality of her life. Because ANGEL has an extremely high pain threshold, she is occasionally able to function when going about her life. On frequent occasions, however, the Pain becomes so great that ANGEL experiences difficulty performing everyday activities, or the Pain is so overpowering that she becomes completely debilitated and cannot get out of bed. When her nervous system becomes too overloaded with Pain, ANGEL experiences Muscle Spasms and Seizures. ANGEL's treatment is complicated by the fact that she is violently allergic to almost all pharmaceutical medicines. Cannabis, however, has the effect of making it easier for ANGEL to tolerate her constant Pain, although it does not make the Pain go away. Without cannabis, ANGEL's Pain would be torturous. On one occasion shortly before she discovered the benefits of cannabis, ANGEL's Pain levels were so high for such a prolonged period of time that, her body and soul racked with agony, ANGEL attempted suicide—as a desperate attempt at the only escape she could perceive from her torment.

A. ANGEL's numerous Pain conditions, as with all her medical conditions, exhibit a complicated interplay between each other, whose exacerbation presents the potential of a vicious spiral. Those Pain conditions include:

B. *Scoliosis*: ANGEL is plagued with abnormal curvatures and a rotation of the spine in her upper back and neck. She will be afflicted with Scoliosis until the day she dies. Scoliosis causes Chronic Pain in the vertebrae and muscles around her spine. The constant

Pain ANGEL experiences from Scoliosis also causes or exacerbates other medical conditions by affecting the musculoskeletal system of the arms, ribs, shoulder, clavicle, neck, and jaw. In addition, the painful site of a recent neck and back injury causes excruciating burning Pain in her vertebrae, nerve problems going down both arms, and difficulties with her thumbs. The injury also caused several of ANGEL's other Pain conditions to worsen. The resulting Pain has caused ANGEL to experience multiple episodes of Seizures and Muscle Spasms (which are painful in their own right) further exacerbating ANGEL's other Chronic Pain conditions and causing new and painful secondary injuries. Perhaps most critically, the injury caused ANGEL to get Fibromyalgia, a pain and fatigue disorder.

C. *Temporomandibular Joint Dysfunction Syndrome (TMJ):* TMJ combined with Bruxism causes pain, aching, throbbing, soreness, spasming, or cramps in ANGEL's face, gums, teeth, and jaw. This can make it difficult to talk, can make her jaw lock closed, can make eating difficult, and can cause headaches. Medical cannabis helps release ANGEL's cramps, relax her muscles, open her mouth, and cope with the Pain. Without medical cannabis, ANGEL's TMJ and Bruxism would spin out of control, worsening her Weight Loss conditions.

D. *Endometriosis:* Endometriosis causes ANGEL to experience disabling excruciating pain, and light headedness due to blood loss, during menstrual periods. ANGEL has undergone seven surgeries for Endometriosis. Immediately following her most recent surgery, ANGEL vaporized with cannabis in the hospital, amazing her doctors and nurses with how fast she recovered relative to patients who use narcotics after surgery.

E. *Headaches*: ANGEL experiences extremely Painful Headaches all over her head. ANGEL wakes up with Headaches nearly every morning. If they are too overpowering she must retreat to a dark quiet place. The muscles in her head and face can go into spasms, exacerbating the Headaches. Vaporizing or smoking cannabis helps ANGEL with Headaches that are not too bad, but the only medication that helps her with Severe Headaches is eating cannabis food.

F. *Rotator Cuff Syndrome*: A work-related injury in 1986 caused ANGEL to get Rotator Cuff Syndrome. Its Burning Pain has worsened over the years. She has difficulty doing repetitive tasks with her right arm, hand, shoulder, and shoulder blade. Overdoing them can cause her shoulder to freeze up and excruciating Burning Pain. Medical cannabis helps ANGEL cope with the Pain, and cannabis makes muscles, tendons, and ligaments around her shoulder joint more pliable, allowing her to use her arm.

G. *Uterine Fibroid Tumor*: ANGEL has a Fibroid Tumor within or on the uterine wall. This causes extremely heavy menstrual bleeding, making ANGEL light headed, dizzy, and nauseous to the point of almost passing out. The heavy bleeding and Painful menstrual periods can keep ANGEL down flat on her back for two or three days per month. Medical cannabis helps minimize ANGEL's pelvic Pain and helps release Spasms and Cramps, allowing her to function more easily.

H. Chronic Pain combined with the Paralysis that confined ANGEL to a wheelchair made her feel that she suffered indescribable torture in Hell. Only medical cannabis, characterized by ANGEL as a miracle sent to her from heaven, delivered ANGEL from the pits of that Hell. Without cannabis, ANGEL would endure the

excruciating torture of Severe Chronic Pain, and she might even again attempt suicide in an effort to escape. Pain, Torture, and Death constitute irreparable harm.

55. *Post Traumatic Stress Disorder P.T.S.D.)*: Years of molestation, physical, and mental abuse by family members created traumas that left ANGEL with Post Traumatic Stress Disorder. Escalated raids by the Defendants on medical cannabis patients since 2001 have exacerbated ANGEL's P.T.S.D. symptoms: She can find herself uncontrollably overwhelmed feeling suddenly in danger, and consumed with feelings of fear, helplessness, and horror. She reexperiences past traumas, has nightmares, and becomes overwhelmed with anxiety. She is becoming increasingly upset, gets angry and aggressive feelings, and fears that she must defend herself before the federal government breaks in her door, attacks her, incarcerates her, or kills her. She experiences sensations of panic and of trying to escape, yet she is too sick and her body is too weak. Medical cannabis helps keep ANGEL from living in the past, helps her deal with flashbacks, and helps her have courage to face her past abuse, her anger, her sadness, and her hurt. Cannabis allows ANGEL to cope with and manage her P.T.S.D. symptoms in a calm safe manner. Experiencing traumatic events (such as learning of new raids by federal agents on medical cannabis patients) can still trigger the P.T.S.D.

56. *Non-Epileptic Seizures:* When ANGEL has a Seizure, she loses awareness, has uncontrollable movements of her arms or legs, shakes all over, and falls to the ground. If she forces herself to go about daily life while having functioning problems, if she moves too fast, or if she becomes frightened for any reason, she can have Seizures. They are extremely

Painful, make all of her Pain conditions worse, and can trigger several of her other conditions. She may suffer for days at a time, having series of Seizures in combination with excruciatingly Painful body jerks, muscle spasms, and twitches. The use of medical cannabis minimizes those symptoms. Medicating with cannabis at the first onset of symptoms can prevent a seizure.

57. *Fibromyalgia:* Fibromyalgia is a condition characterized by multiple serious conditions. It causes ANGEL widespread chronic Pain in her muscles, ligaments, and tendons. Every muscle in her body can scream out Pain. The Pain can overload her body, putting her flat on her back for days. Fibromyalgia also causes extreme fatigue, totally draining ANGEL of energy, as though her arms and legs are tied to concrete blocks, and making it difficult to concentrate. Fibromyalgia further causes a sleep disorder inhibiting deep levels of sleep, as if ANGEL spends nights with one foot in sleep and the other one out of it. Other Fibromyalgia symptoms ANGEL experiences include Premenstrual Syndrome, Painful periods, chest Pain, severe morning Stiffness, Cognitive Functioning Problems, Numbing in her arms and legs, Tingling sensations, muscle Twitching, Skin Sensitivity, Dizziness, Impaired Coordination, losing her balance, and stumbling. Medical cannabis makes ANGEL's muscles, tendons, and ligaments more pliable, allowing her to move and go about her life with her family. It also helps her cope with the Chronic Pain and makes physical therapy more effective.

58. *Inoperable Brain Tumor:* ANGEL has a Meningioma or Schwannoma Brain Tumor. The Tumor is too deep for surgeons to remove it. In research suppressed by Defendants, researchers found that THC

(one component in medical cannabis) slowed the growth of Cancer in Mice. Later research (conducted outside the United States) confirmed that THC can destroy Brain Tumors in rats. ANGEL's doctors want her to continue medicating with cannabis in the hope that, among its other benefits, it will prevent her Brain Tumor from growing.

59. *Paralysis*: In September 1995, ANGEL suddenly lost the use of her right leg. By 1996, ANGEL was paralyzed on the right side of her body. For two years, her doctors could not diagnose the cause of her paralysis or prescribe an effective treatment. They said ANGEL would never walk again. In 1998, the use of high quality cannabis allowed sensation slowly to return to ANGEL's right side. Finally, in 1999 ANGEL regained use of her arm and leg and eventually learned to walk again in a difficult process made possible by cannabis.

Supreme Court, U.S.
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No. 03-1454

IN THE

Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
Petitioners,

v.

ANGEL McCLARY RAICH, ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTION PRESENTED

Respondents are two seriously ill California patients and caregivers to one of the patients. Respondents possess or cultivate cannabis solely to be used by the patients for medical purposes, as recommended by the patients' physicians and authorized by the California Compassionate Use Act, Cal. Health & Safety Code § 11362.5. The medical cannabis is cultivated using only materials originating from or manufactured within the State of California. The question presented is:

Whether the court of appeals properly concluded that Respondents are entitled to a preliminary injunction preventing Petitioners from taking action to enforce the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, against them based upon: (1) the likelihood that Respondents will succeed on the merits of their claim that the Controlled Substances Act, as applied to them, exceeds Congress's power under the Commerce Clause; (2) the likelihood that Respondents will succeed on the merits of their additional claims under the Due Process Clause of the Fifth Amendment, the Ninth and Tenth Amendments, and the medical necessity doctrine; and (3) the findings of both courts below that the balance of hardships and the public interest tip sharply in favor of Respondents, such that a preliminary injunction is warranted based upon the existence of a serious question going to the merits.

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States, and Karen P. Tandy, Administrator of the Drug Enforcement Administration.

Respondents are Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two.

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Respondents agree with Petitioners that this case presents questions of great public importance. For several reasons, however, the Court should not grant immediate review. The court of appeals' decision is interlocutory, and this Court would benefit greatly from a full factual record. In addition, there are alternate grounds on which the entry of a preliminary injunction would be proper even if this Court were to disagree with the court of appeals' preliminary ruling on the Commerce Clause. Finally, Petitioners have failed to demonstrate that immediate review is imperative.

STATEMENT OF THE CASE

1. a. California is one of nine States that have enacted laws approving the use of cannabis for medical purposes. *See* Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5 (West Supp. 2004).[1] The purpose of the

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[1] The other States are Alaska, Colorado, Hawaii, Maine, Nevada, Oregon, Vermont, and Washington. *See* Alaska Stat. §§ 11.71.090, 17.37.010 *et seq.* (Michie 2003); Colo. Const. Art. 18, § 4; Haw. Rev. Stat. Ann. § 329-121 *et seq.* (Michie Supp. 2003); Me. Rev. Stat. Ann. tit. 22, § 2383-B (West 2004); Nev. Rev. Stat. Ann. § 453A.200 (Michie Supp. 2003); Or. Rev. Stat. §§ 475.300-.346 (2003); Vt. Stat. Ann. tit. 18 § 4272 *et seq.* (2004); Wash. Rev. Code Ann. §§ 69.51.010-.080 (West 2004). Five other States have enacted laws that recognize the therapeutic benefits of cannabis but authorize use only by prescription, *see* Ariz. Rev. Stat. § 13-3412.01 (West 2004); La. Rev. Stat. Ann. § 40:1201 (West 2003); N.H. Rev. Stat. Ann. § 318-B:10(VI) (2003); Va. Code Ann. § 18.2-251.1 (Michie 2003), or that classify cannabis as having "currently accepted medical uses" without authorizing such uses, *see* Iowa Code §§ 124.205, 124.206(7)(a) (West 2003). Efforts to enact compassionate use laws are underway in at least nine other States, including Connecticut, Florida, Illinois, Missouri, Montana, New York, Rhode Island, Utah, and Wisconsin, and in the District of Columbia. *See also* Coleen McMurray, *Medicinal Marijuana: Is It What the Doctor Ordered?*, Gallup Poll Tuesday Briefing (Dec. 16, 2003) (75% of Americans support allowing physicians to prescribe cannabis to patients "to ease pain and suffering").

Compassionate Use Act is "[t]o ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where the medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief." *Id.* § 11362.5(b)(1)(A). The Act permits a patient, or the patient's primary caregiver, to possess or cultivate cannabis for the patient's personal medical purposes upon the recommendation or approval of a physician. *Id.* § 11362.5(d).

b. The federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, ("CSA") makes it a crime to possess any controlled substance except as authorized by the CSA. 21 U.S.C. § 844(a). Although marijuana is classified as a schedule I drug with "no currently accepted medical use in treatment in the United States," *id.* § 812(b)(1)(B), (c),[2] "the public record reflect[s] a legitimate and growing division of informed opinion on this issue." *Conant v. Walters*, 309 F.3d 629, 640 (9th Cir. 2002) (Kozinski, J., concurring), *cert. denied*, 124 S. Ct. 387 (2003). "A surprising number of health care professionals and organizations have concluded that the use of marijuana may be appropriate for a small class of patients who do not respond well to, or do not tolerate, available prescription drugs." *Id.* at 640-41. For example, a

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[2] Federal law defines "marihuana" to mean "all parts of the plant Cannabis sativa L." except "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, . . . or the sterilized seed of such plant." 21 U.S.C. § 802(16). In this brief, the term "cannabis" refers to any part of the plant Cannabis sativa L. used for medical purposes.

study commissioned by the White House Office of National Drug Control Policy and carried out by the National Institute of Medicine (a component of the National Academy of Sciences) concluded that "the accumulated data suggest a variety of indications, particularly for pain relief, antiemesis, and appetite stimulation," and that "[f]or patients such as those who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication." Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base* 177 (Janet E. Joy *et al.* eds., 1999), *available at* http://www.nap.edu/books/0309071550/html. The study further concluded that "[u]ntil a nonsmoked rapid-onset cannabinoid drug delivery system becomes available," "there is no clear alternative for people suffering from *chronic* conditions that might be relieved by smoking marijuana, such as pain and AIDS wasting." *Id.* at 179 (emphasis in original). Accordingly, the study endorsed treatment of such patients with smoked marijuana subject to an oversight mechanism. *See id.* at 179. Other studies have reached similar conclusions. *See Conant*, 309 F.3d at 640-43 (Kozinski, J., concurring) (summarizing the scientific evidence supporting limited medical use of cannabis, and its acceptance by, among others, the British House of Lords and the Canadian government).[3]

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[3] Surprisingly, Petitioners fail to acknowledge the existence of this evidence, and also quote, without qualification, statements that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition" and "there are no FDA-approved marijuana products." Pet. 17 n.4 (quoting 66 *Fed. Reg.* 20,038 (Apr. 18, 2001)). As to the latter statement, Marinol is an FDA-approved product, and the active ingredient of Marinol is the cannabinoid THC, one of the primary psychoactive compounds in marijuana. *See Marijuana and Medicine* 137, 202-07.

2. Respondents are California citizens who cultivate or use cannabis for medical treatment on the recommendation of their physicians and pursuant to the Compassionate Use Act. Pet. App. 46a. Respondents Angel Raich and Diane Monson each suffer from serious medical conditions. Both courts below found that "[t]raditional medicine has utterly failed these women." *Id.* at 5a, 46a. Respondents John Doe Number One and John Doe Number Two are Raich's caregivers.

a. Respondent Angel Raich suffers from a daunting array of serious medical conditions including "life-threatening weight loss, nausea, severe chronic pain (from scoliosis, temporomandibular joint disfunction and bruxism, endometriosis, headache, rotator cuff syndrome, uterine fibroid tumor causing severe dysmenorrheal, chronic pain combined with an episode of paralysis that confined her to a wheelchair), post-traumatic stress disorder, non-epileptic seizures, fibromyalgia, inoperable brain tumor (probable meningioma or Schwannoma), paralysis on at least one occasion (the diagnosis of multiple sclerosis has been considered), multiple chemical sensitivities, allergies, and asthma." App., *infra*, 2a (Decl. of Frank Henry Lucido, M.D.)[4]

Raich's physician, a Board-certified family practitioner, states that his patient "has tried essentially all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects." App., *infra*, 3a. Raich's physician has submitted a list of 35 medications that Raich has tried, all of which "resulted in unacceptable adverse side effects." *Id.* The physician has concluded that "Angel has no reasonable legal alternative to cannabis for

[4] The declarations of Angel Raich, Diane Monson and their physicians are attached as an appendix to this brief.

effective treatment or alleviation of her medical conditions or symptoms." *Id.*

From 1996 to 1999, Raich was partially paralyzed and confined to a wheelchair. App., *infra*, 14a, 24a, 26a-27a (Decl. of Angel Raich). In August 1997, after her physician concluded that her pain could not be controlled using conventional medications, Raich attempted suicide to end her pain and suffering. *Id.* at 26a; Pet App. 93a.

Thereafter, Raich began using cannabis on her physician's recommendation, and her medical condition improved significantly. She is no longer confined to a wheelchair. App., *infra*, 24a-25a. She is better able to cope with her medical conditions and plays a more active role in the lives of her two children. *Id.* at 15a-16a, 41a.

Raich's physician has concluded that his patient may die if she is denied medical cannabis. App., *infra*, 4a-5a ("It could very well be fatal for Angel to forego cannabis treatments."). The physician also states: "It is my opinion that Angel cannot be without cannabis as medicine because of the precipitous medical deterioration that would quickly develop." *Id.* at 2a. "She clearly loses weight, and would risk wasting syndrome and death, without cannabis." *Id.* In addition, "Angel becomes debilitated from severe chronic pain. *Id.*[5]

[5] The Petition refers to Respondents' "purported personal 'medicinal' use" of marijuana. Pet. i. By placing "medicinal" in quotation marks and referring to "purported" medicinal use, Petitioners imply that Respondents may not be using cannabis for medical purposes. This implication is unwarranted. Respondents have submitted evidence that they are using cannabis for bona fide medical purposes, and Petitioners have not disputed that evidence. At this stage of the proceedings, Petitioners must accept the record as it stands.

b. Respondent Diane Monson suffers from severe, chronic back pain and constant painful muscle spasms caused by a degenerative disease of the spine. Pet. App. 5a. Monson's physician, who is also Board-certified in family practice, states that "Diane has tried other medical alternatives to medical cannabis, including Flexeril, a muscle relaxant, and Feldene, a powerful anti-inflammatory," but "those prescription drugs have proven to be either ineffective in relieving Diane's pain and suffering or produce intolerable side effects." App., *infra*, 7a (Decl. of John Rose, M.D.). Dr. Rose reports that he "prescribed Vicodin and Vioxx to attempt to relieve Diane's pain and suffering," but "Vicodin, an addictive drug," "leaves her with an extremely sick stomach for several days after any use." *Id.* Vioxx "appears to relieve Diane's inflammation associated with her back pain" but "does not relieve her painful spasms." *Id.* Dr. Rose has determined "that medical cannabis use is deemed appropriate for Diane Monson, and that medical cannabis provides necessary relief for Diane's pain and suffering." *Id.* Accordingly, "pursuant to California state law, medical cannabis was recommended for Diane as treatment of her medical conditions, including her Chronic Back Pain and Spasms." *Id.* Cannabis "virtually eliminates" Diane's muscle spasms and "greatly relieves" her back pain. *Id.* at 11a (Decl. of Diane Monson). Without cannabis, Diane would suffer "intense pain" that would make working or even sitting down "impossible," and would relegate her to lying down. *Id.* at 10a-11a.[6]

c. Angel Raich's cannabis is grown using only soil, water, nutrients, growing equipment, supplies, and lumber originating from or manufactured within California. Pet.

[6] The record refutes Petitioners' suggestion that medical cannabis may induce patients "to refrain from consuming lawful drugs." Pet. 13 n.3. There is no alternative to cannabis for Respondents.

App. 47a. Diane Monson's "cultivation of marijuana is similarly local in nature." *Id.* Diane Monson cultivates her own cannabis. *Id.* at 46a. Angel Raich is unable to cultivate cannabis. *Id.*; App., *infra*, 30a-31a (Raich Decl.). She therefore relies on two caregivers, Respondents John Doe Number One and John Doe Number Two, to cultivate her cannabis for her. Pet. App. 5a, 46a; App., *infra*, 36a (Raich Decl.). Raich processes some of the plants into cannabis oils, balm, and foods. Pet. App. 5a. Raich's caregivers grow cannabis specifically for Raich, pursuant to her instructions and on her physician's written recommendation. App., *infra*, 36a-38a (Raich Decl.). The caregivers cultivate Raich's cannabis for her completely free of charge. *Id.* at 37a.[7]

On August 15, 2002, deputies from the Butte County Sheriff's Department and agents from the Drug Enforcement Administration ("DEA") came to Monson's home, where they found six cannabis plants. Pet. App. 6a. The deputies concluded that Monson's use of cannabis was legal under the Compassionate Use Act. *Id.* Following a "three-hour standoff" involving the Butte County District Attorney and the U.S. Attorney for the Eastern District of California, the

[7] Petitioners incorrectly describe the activities at issue in this case as including the "distribution without charge of marijuana." Pet. 8. The CSA defines "distribute" to mean "to deliver (other than by administering or dispensing)," and defines "deliver," in turn, as "the actual, constructive, or attempted transfer of a controlled substance." 21 U.S.C. § 802(8), (11). Diane Monson cultivates cannabis for her own use; there clearly is no "distribution" in her case. It is also a significant stretch to view the cultivation of cannabis by Angel Raich's caregivers as "distribution." Cultivating a neighbor's vegetable garden is not the same as distributing the vegetables. The court of appeals' narrower description of the activities at issue in this case is more accurate: "the intrastate cultivation, possession and use of medical marijuana on the recommendation of a physician." Pet. App. 11a.

DEA agents seized and destroyed Monson's cannabis plants. *Id.*

2. Respondents brought this action contending that it is unlawful to apply the CSA to prevent them from possessing and cultivating cannabis for personal medical purposes, as recommended by their physicians and permitted by State law. Respondents contend that applying the CSA to their activities would violate the Commerce Clause, the Due Process Clause of the Fifth Amendment, the Ninth Amendment, the Tenth Amendment, and the doctrine of medical necessity. Respondents filed a motion for a preliminary injunction, which the district court denied. Pet. App. 45a. The district court found that the balance of hardships and the public interest tip sharply in favor of granting injunctive relief. *Id.* at 67a-68a (the interests asserted by the federal government "wane in comparison with the public interests enumerated by plaintiffs and by the harm that they would suffer if denied medical marijuana" and Respondents have submitted "strong evidence that [they] will suffer severe harm and hardship if denied use of [cannabis]").

The district court nevertheless denied the motion for a preliminary injunction, on the ground that Respondents are "unable, on this record, to establish the required 'irreducible minimum' of a likelihood of success on the merits." Pet. App. 68a. On the Commerce Clause claim, the district court regarded itself as "bound by existing Ninth Circuit authority" upholding the CSA in non-medical contexts. *Id.* at 57a. The district court also held that Respondents are unlikely to prevail on their other claims. *Id.* at 58a-65a.

3. The court of appeals reversed. It agreed with the district court that "[t]here can be no doubt on the record as to the significant hardship that will be imposed on the patient-appellants if they are denied a preliminary injunction." Pet. App. 24a. Indeed, Petitioners "do not dispute this." *Id.* The court found that "[t]he public interest of the state of

California and its voters in the viability of the Compassionate Use Act also weighs against the [Petitioners'] concerns." *Id.* at 25a.

The court of appeals determined that Respondents are likely to prevail on the merits of their claim that the CSA, as applied to them, exceeds Congress's power under the Commerce Clause. Pet. App. 23a. The court of appeals noted that "the way in which the activity or class of activities is defined is critical." *Id.* at 11a. The court determined that "the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician" is a class of activities separate and distinct from drug trafficking. *Id.* The court observed that "concern regarding users' health and safety is significantly different in the medical marijuana context, where the use is pursuant to a physician's recommendation"; "limited medical use of marijuana as recommended by a physician arguably does not raise the same policy concerns regarding the spread of drug abuse"; and "this limited use is clearly distinct from the broader illicit drug market – as well as any broader commercial market for medical marijuana – insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." *Id.*

Applying the four-factor analysis set out in *United States v. Morrison*, 529 U.S. 598 (2000), the court held that the cultivation, possession and use of cannabis for medicinal purposes is not properly characterized as commercial or economic activity because it does not involve an "'exchange of goods and services, esp. on a large scale involving transportation between cities, states, and nations.'" Pet. App. 14a (quoting *Black's Legal Dictionary* (7th ed. 1999) (defining "commerce")). The court concluded that it is not appropriate to apply the "aggregation principle" of *Wickard v. Filburn*, 317 U.S. 111 (1942), to activity that is non-commercial in character. Pet. App. 15a.

Second, the court of appeals noted, the CSA lacks a "jurisdictional hook" that would limit its application to "cases that substantially affect interstate commerce." Pet. App. 18a. Third, although the CSA includes general findings concerning the effects of intrastate activity on interstate commerce, those findings "are not specific to marijuana, much less intrastate medicinal use of marijuana that is not bought or sold and the use of which is based on the recommendation of a physician." *Id.* at 19a.

Finally, "the link between the regulated activity and a substantial effect on interstate commerce is 'attenuated.'" Pet. App. 21a. Even if the intrastate cultivation, possession, and use of medical cannabis on the recommendation of a physician could affect interstate commerce "at the margins" by *reducing* demand for marijuana that is trafficked interstate, "[i]t is far from clear that such an effect would be substantial." *Id.* at 21a-22a.

The court of appeals held that the likelihood the Respondents will prevail on the merits of their Commerce Clause claim, in conjunction with "public interest considerations and the burden faced by [Respondents] if, contrary to California law, they are denied access to medicinal marijuana, warrants the entry of a preliminary injunction." *Id.* at 26a. The court determined that its ruling is "sufficiently narrow to avoid" concerns that other plaintiffs seeking to use schedule I controlled substances will bypass the procedures established by Congress. The court found that Petitioners' "speculative slippery slope concern is weak in comparison to the real medical emergency facing the patient-appellants in this case." *Id.*

Judge Beam dissented. Pet. App. 26a-43a. He questioned whether Respondents' claims are ripe and whether they have standing to pursue this action. Because these issues were "not briefed or argued by the parties, or mentioned by the district court," Judge Beam would have

remanded to allow the district court to consider whether there is an Article III case or controversy. *Id.* at 30a. On the merits, Judge Beam concluded that "[i]t is simply impossible to distinguish" this case from *Wickard*. *Id.* at 26a.

REASONS WHY THE PETITION SHOULD BE DENIED

1. Respondents agree with Petitioners that this case presents questions of great importance. For several reasons, however, the Court should not grant review at this stage of the proceedings.[8]

First, the order of the court of appeals is interlocutory. The court of appeals' preliminary ruling is based on a limited factual record. Further proceedings in the district court will produce a more complete record and findings of fact. *See Sabri v. United States*, 124 S. Ct. 1941, 1948 (2004) (warning against deciding cases based on "factually barebones records"). A complete factual record is likely to shed light on a range of issues in this case, including whether the activities of similarly-situated individuals substantially affect interstate commerce. After the district court enters a final judgment based on a complete factual record, the Commerce Clause issue will be reconsidered by the court of

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[8] The Petition does not address Judge Beam's recommendation that the case be remanded to the district court to address factual issues related to ripeness and standing. *See* Pet. App. 26a-31a. Respondents believe that they have standing and that their claims are ripe, and Petitioners' silence on these issues indicates that they agree. The Court nevertheless has an obligation to consider Article III standing in every case, regardless of the views of the parties. Additional facts relevant to Article III requirements may be developed on remand.

appeals, and may be considered by that court en banc or by this Court.[9]

Second, if this Court granted immediate review, it might have no effect on the outcome of Respondents' motion for a preliminary injunction. Under the standard applied in the Ninth Circuit, where the balance of hardships and the public interest tip sharply in favor of the moving party, the court will grant a preliminary injunction if the movant can show the existence of "serious questions going to the merits." *Id.* (citing *First Brands Corp. v. Fred Meyer, Inc.*, 809 F.2d 1378, 1381 (9th Cir. 1987)). Both courts below found that the hardship and public interest factors tip sharply in Respondents' favor. *See* Pet. App. 24a, 68a. Petitioners do not challenge these findings. Thus, in order to obtain a preliminary injunction, Respondents are not required to show that they will prevail on the merits, or even that they are likely to prevail on the merits. Respondents must show only that there are serious questions going to the merits.

Respondents could satisfy this relatively undemanding standard even if the Court were to grant immediate review and agree with some or all of Petitioners' legal arguments. For example, the Court could conclude that the Commerce Clause issues ultimately turn on factual questions, such as whether seriously ill patients who take locally grown cannabis for medical purposes, considered in the aggregate, have a substantial effect on interstate commerce. In that event, the preliminary injunction might well remain in effect pending further factual development and entry of a final judgment. Moreover, Respondents have asserted several

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[9] The interlocutory nature of the court of appeals' decision, and the importance of a fully-developed record, may explain why not a single judge of the court of appeals requested a vote on whether to rehear the matter en banc at this stage. *See* Pet. App. 70a.

additional grounds for injunctive relief. If even one of these claims raises "serious questions going to the merits," the preliminary injunction would remain in effect even if this Court were to grant interlocutory review and issue a definitive ruling in Petitioners' favor on the Commerce Clause claim.

Third, the court of appeals' decision does not conflict with any decision of another court of appeals. None of the decisions of courts of appeals upholding the CSA against a Commerce Clause challenge, including prior decisions of the Ninth Circuit, "involved the use, possession, or cultivation of marijuana for medical purposes." Pet. App. 10a. Petitioners contend that, for Commerce Clause purposes, medical use should not be distinguished from non-medical use. But that is precisely the question addressed by the court of appeals' preliminary decision. To date, no other court of appeals has even considered that question, let alone disagreed with the Ninth Circuit. Accordingly, Petitioners are incorrect in asserting that the court of appeals' decision creates a conflict in the circuits.[10]

2. This Court has "emphasized" that "Congress' regulatory authority" under the Commerce Clause "is not without effective bounds," *Morrison*, 529 U.S. at 608, and "'may not be extended . . . [to] effectually obliterate the distinction between what is national and what is local and create a completely centralized government.'" *United States v. Lopez*, 514 U.S. 549, 556-57 (1995) (quoting *NLRB v.*

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[10] Petitioners are also incorrect in asserting (Pet. 18) that the court of appeals' decision conflicts with this Court's decision in *United States v. Oakland Cannabis Buyers' Cooperative* ("*OCBC*"), 532 U.S. 483 (2001). In *OCBC*, the Court expressly stated that it was not "passing today on a constitutional question, such as whether the Controlled Substances Act exceeds Congress' power under the Commerce Clause." *Id.* at 494 n.7.

Jones & Laughlin Steel Co., 301 U.S. 1, 37 (1937)). In this case, as in *Morrison* and *Lopez*, Petitioners make no attempt to defend the federal statute based on "use of the channels of interstate commerce," "the instrumentalities of interstate commerce, or persons or things in interstate commerce." *Morrison*, 529 U.S. at 609 (internal quotation marks and citations omitted). Accordingly, if application of the CSA to Respondents can be justified, it is only on the ground that Respondents' activities "substantially affect interstate commerce." *Id.* On the present record, Petitioners cannot make such a showing.

a. Petitioners quote Judge Beam's statement that "[i]t is simply impossible to distinguish the relevant conduct" in this case "from the cultivation and use of the wheat crop that affected interstate commerce in *Wickard*." Pet. 7-8 (quoting Pet. App. 26a). In fact, this case is distinguishable from *Wickard* on several grounds. Indeed, a decision upholding Congress's exercise of the Commerce Power in this case would represent a significant extension of *Wickard*.

First, *Wickard*, unlike this case, involved a commercial operation – a farm. The farm's "wheat acreage allotment" for 1941 under the Agricultural Adjustment Act was 11.1 acres, which at a "normal yield" for 1941 of "20.1 bushels of wheat an acre," yielded 221 bushels (or 13,260 pounds) of wheat.[11] 317 U.S. at 114. The farm actually planted 23 acres of wheat – more than double its allotment. *Id.* The 11.9 excess acres produced 239 bushels of wheat, bringing the farm's total wheat production to 460 bushels, or 27,600 pounds. *Id.* The excess wheat alone was far more than the

[11] 317 U.S. at 114. One bushel of wheat weighs approximately 60 pounds and yields approximately 60 pounds of whole-wheat flour or 42 pounds of white flour. Wheat Foods Council, *Grains of Truth About Wheat*, http://www.wheatfoods.org/docs/Grains_Truth_Wheat_Facts.doc (last visited June 5, 2004).

farmer and his family could consume. Some of the excess wheat was sold as a commodity. A portion of the excess wheat was fed to livestock and the livestock – or the milk and eggs they produced – were sold as commodities. *Id.*

Respondents, unlike the farm in *Wickard*, are not engaged in farming or any other commercial enterprise. They do not sell, barter, or exchange cannabis, or use it to produce any other product that they sell, barter, or exchange. Diane Monson cultivates only enough cannabis for her own medical use, while Angel Raich's caregivers cultivate her cannabis specifically for her, without any charge, for compassionate rather than economic reasons. The quantities involved are small compared to those in *Wickard*. *See* Pet. App. 6a (federal agents seized six cannabis plants).

Second, unlike the law at issue here, the federal law in *Wickard* exempted small commercial farms, and certainly exempted wheat grown in home gardens for personal use. *See* 317 U.S. at 130 & n.30 (citation omitted). At the time the wheat at issue in *Wickard* was planted, "small producers" were defined as those that produced "less than 200 bushels" (12,000 pounds) of wheat. *Id.* By the time the wheat was harvested, the definition had been amended to exempt up to 15 acres of wheat, enough to produce 300 bushels (18,000 pounds) of wheat. *See* 54 Stat. 232. In this case, there is no such exemption.

Third, the evidence in *Wickard* demonstrated that the commercial activity of the farmer and others similarly situated had a substantial aggregate effect on interstate commerce. As the government's brief in *Wickard* explained, in the years immediately before Congress enacted the Agricultural Adjustment Act, nearly 30 percent of the nation's wheat was used on the farm where it was grown. *See* Br. of Appellants in No. 59, *Wickard v. Filburn*, at 12 (from "1931-32 to 1935-36," the "average production of wheat in the United States was 680,603,000 bushels,"

"484,673,000 bushels" of which were "sold from the farm"; the remaining 195,930,000 bushels (28.8%) were fed to livestock, used as seed, or used in the household on "the farm where grown").[12] The Court's opinion in *Wickard* left no doubt that the aggregate effect of this activity on interstate commerce was a critical factor in the Court's decision. *See* 317 U.S. at 128 ("It can hardly be denied that *a factor of such volume and variability* as home-consumed wheat would have a substantial influence on price and market conditions.") (emphasis added), *quoted in Lopez*, 514 U.S. at 560.

In this case, in contrast, it is "far from clear" that seriously ill individuals who cultivate small amounts of cannabis for their own medical use, on a doctor's recommendation and pursuant to State law, have any substantial aggregate effect on interstate commerce. Pet. App. 22a. Cannabis patients make up a negligible percentage of marijuana users. *See* United States General Accounting Office, *Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes* 21 (Nov. 2002), *available at* http://www.gao.gov/new.items/d03189.pdf ("Relatively few people are registered as medical marijuana users in Alaska, Hawaii and Oregon. In these States, registry data showed that the number of participants registered was 0.05 percent or less of the total population of each respective state.").[13] The GAO's report does not include statewide data

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[12] By the time the Court decided *Wickard*, the percentage had dropped, but it still represented more than one-fifth of the volume of wheat produced nationwide. Br. of Appellants on Reargument in No. 59, *Wickard v. Filburn*, at 3 (22 percent of the wheat grown in 1940 was not sold).

[13] Only 364 of the more than 4,300,000 people who live in Colorado – 0.0008% – have a valid medical marijuana identification card. Colorado Dep't of Public Health and Environment, *Medical Marijuana Registry Program Update* (Apr. 30, 2004), *available at* http://www.cdphe.state.co.us/hs/Medicalmarijuana/marijuanaupdate.asp; (continued...)

for California, but it does include data for four California counties. In each of these counties, cannabis patients represent less than one-half of one percent of the population.[14]

This case is thus quite different from *Wickard*, where the regulated enterprise and similarly-situated enterprises represented over one-fourth of the nationwide wheat market, so that applying the federal law to the farm at issue and all similarly situated farms was "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561.[15]

U.S. Census Bureau, *Colorado: 2000* (Aug. 2002), *available at* http://www.census.gov/prod/2002pubs/c2kprof00-co.pdf. Only 8,975 of the more than 3.5 million residents of Oregon – less than 0.03 percent – hold a state-issued card allowing them to grow and possess marijuana for personal medical use. Oregon Dep't of Human Services, *Oregon Medical Marijuana Program: Statistics* (Apr. 1, 2004), http://www.dhs.state.or.us/publichealth/mm/data.cfm.

[14] This is so even though one of the four jurisdictions is San Francisco County, an urban county with an especially high number of AIDS patients. As of January 31, 2003, of the 61,013 California residents with AIDS, 8,131 – over 13% – lived in San Francisco. *See* California Prevention Services, Office of AIDS, *AIDS Case Archives*, http://www.dhs.ca.gov/aids/Statistics/default.htm (last visited June 5, 2004).

[15] There are other differences between this case and *Wickard*. In *Wickard*, applying the Agricultural Adjustment Act to the farm and similarly situated farms furthered the federal government's objective of increasing the price of wheat. In this case, in contrast, applying the CSA to Respondents and other similarly situated patients will not further the government's objective of eliminating interstate commerce in marijuana – indeed, it may have the opposite effect if patients are driven to purchasing cannabis rather than cultivating it themselves. Furthermore, the farmer in *Wickard benefited* from the marketing quotas, which increased the price of his wheat. In a referendum of wheat growers, 81 percent *voted* in favor of the marketing quotas. 317 U.S. at 116. The farmer in *Wickard* (continued...)

This Court has observed that *Wickard* is "perhaps the most far reaching example of Commerce Clause authority over intrastate activity." *Lopez*, 514 U.S. at 561. At some point, the Court might well conclude that it is appropriate to narrow the holding of *Wickard*. In this case, however, the issue is whether *Wickard* should be substantially *expanded*.

b. In *Morrison* the Court identified four "reference points" that guide analysis of whether an activity "substantially affects" interstate commerce: (1) whether the federal law at issue is "a criminal statute that by its terms has nothing to do with 'commerce' or any sort of economic enterprise"; (2) whether the federal statute lacks an "express jurisdictional element which might limit its reach to a discrete set of . . . possessions that additionally have an explicit connection with or effect on interstate commerce"; (3) whether there are no "express congressional findings regarding the effects upon interstate commerce" of the activity in question; and (4) whether "the link between [the activity] and a substantial effect on interstate commerce [i]s attenuated." 529 U.S. at 610-12. The differences between this case and *Wickard* support the conclusion that Respondents' activity does not substantially affect interstate commerce.

First, this Court observed in *Morrison* that "in every case where we have sustained federal regulation under the aggregation principle in *Wickard*, the regulated activity was of an apparent commercial character" and involved "some sort of economic endeavor." 529 U.S. at 611 & n.4 (internal citation omitted). In this case, unlike *Wickard*, Respondents

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faced only a $117.17 fine. *Id.* at 115. Here, in contrast, both courts below found that Respondents will be severely *harmed* by application of the CSA; the citizens of California *voted* to permit limited medical use of cannabis; and Respondents face not a modest fine but imprisonment, large forfeitures, fines, excruciating pain, and possibly death.

are not engaged in an activity of a "commercial character" or in an "economic endeavor." They do not sell, barter, or exchange cannabis, or use it as an input for any other product that they sell, barter, or exchange. Diane Monson cultivates only enough cannabis to meet her own medical needs, on her doctor's recommendation, to "make the difference between a relatively normal life and a life marred by suffering." *Conant v. Walters*, 309 F.3d at 643 (Kozinski, J., concurring). Angel Raich does the same, relying on caregivers to cultivate her cannabis because she is too ill to do so on her own. Raich's caregivers cultivate her cannabis as an act of compassion. They do not receive payment or any item of economic value for their efforts. This activity, undertaken to avoid excruciating pain and prolong life, is "activity beyond the realm of commerce in the ordinary and usual sense of that term." *Lopez*, 514 U.S. at 583 (Kennedy, J., joined by O'Connor, J., concurring).

Second, the CSA lacks any "express jurisdictional element" that could "ensure, through case-by-case inquiry, that the [activity] in question affects interstate commerce." *Id.* at 561-62.

Third, the CSA contains no specific findings concerning cannabis, let alone findings directed to local cultivation and use of cannabis solely for treatment of seriously ill patients, as recommended by a doctor and regulated by State law. To be sure, the CSA contains general findings that any possession or use of any controlled substance, except as authorized by federal law, substantially affects interstate commerce. *See* 21 U.S.C. § 801. But "the existence of congressional findings is not sufficient, by itself, to sustain the constitutionality of Commerce Clause legislation." *Morrison*, 529 U.S. at 614. "Whether particular operations affect interstate commerce sufficiently to come under the constitutional power of Congress to regulate them is ultimately a judicial rather than a legislative question." *Id.* Congress's generalized and conclusory findings cannot

decide the judicial question presented by this case: whether cultivation, possession, and use of small quantities of cannabis, by seriously ill patients as medication, on a doctor's recommendation and as permitted by State law, substantially affects interstate commerce. The record at this point strongly supports the conclusion that locally cultivated medical cannabis is *not* transported in interstate commerce, does *not* swell interstate trafficking in marijuana, and may well be distinguishable from marijuana that is transported in interstate commerce based upon the system of regulation established by California law. The evidence produced so far therefore indicates that federal control of medical cannabis cultivated pursuant to California's Compassionate Use Act is not "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561.

Fourth, the link between Respondents' activity and interstate commerce is attenuated at best. Respondents function outside any commercial market. They cultivate small amounts of cannabis for personal medical use; they do not sell, barter, or exchange cannabis, in interstate commerce or otherwise. The only individuals involved, other than the two patients, are Raich's caregivers, and they receive no payment or anything of tangible value in return for cultivating Raich's cannabis specifically for her. Pet. App. 14a n.3 ("'My caregivers grow my medicine specifically for me. They do not charge me, nor do we trade anything.'") (quoting App., *infra*, 37a (Raich Decl.)).

c. Petitioners do not argue that Respondents' activities, considered by themselves, substantially affect interstate commerce. Nor do they seriously contend, given the present record, that the activities of similarly-situated patients considered in the aggregate substantially affect interstate commerce. Petitioners therefore are relegated to an argument that Respondents' activities "are part of the overall class of

activities regulated by Congress" under the CSA – *i.e.*, the manufacture, possession, and distribution of controlled substances – and this broader class of activities involves economic activity and substantially affects commerce. Pet. 12.

If Petitioners' argument were accepted, there would be no limit on the reach of the Commerce Clause power. That is so because "one always can draw the circle broadly enough to cover an activity that, when taken in isolation, would not have substantial effects on commerce." *Lopez*, 514 U.S. at 560 (Thomas, J., concurring). *See also Morrison*, 529 U.S. at 657 (Breyer, J., dissenting) (noting that if Commerce Clause analysis depends on the class of activities addressed by the federal statute, Congress could shield the Violence Against Women Act from Commerce Clause scrutiny by incorporating it "in a broader 'Safe Transport' or 'Workplace Safety' act"). In *Lopez* and *Morrison*, this Court rejected reasoning under which "Commerce Clause authority would effectively know no limit." *Sabri*, 124 S. Ct. at 1947. Consequently, Petitioners' argument must be rejected.

If Petitioners were correct, there would be no such thing as an as-applied challenge under the Commerce Clause. In fact, however, this Court "has always entertained" such challenges. *United States v. Stewart*, 348 F.2d 1132, 1141 (9th Cir. 2003). *Wickard* itself was an as-applied challenge. "Had the Court deemed regulation of the business of agriculture a sufficient basis for upholding the application of the Agricultural Adjustment Act to Filburn, there would have been no need for it to analyze how *his* particular activities affected interstate commerce." *Id.* Similarly, in considering whether Title II of the Civil Rights Act exceeded Congress's powers under the Commerce Clause, the Court separately considered whether the statute was valid "as applied . . . to a motel which concededly serves interstate travelers," *Heart of Atlanta Motel v. United States*, 379 U.S. 241, 261 (1964), and "as applied to a restaurant annually receiving about

$70,000 worth of food which has moved in commerce." *Katzenbach v. McClung*, 379 U.S. 294, 298 (1964). If the Court had considered only the entire class of activities covered by Title II, it would have decided only one case, not two, and it would not have considered "whether *a single hotel or restaurant* had a sufficient nexus to interstate commerce, and thus could be federally regulated." *Stewart*, 348 F.3d at 1141-42. *See also Solid Waste Agency v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173 (2001) (noting that to address the Commerce Clause issue the Court "would have to evaluate the precise object or activity that, in the aggregate, substantially affects interstate commerce").

Accordingly, Petitioners cannot prevail in this case by invoking the principle that "[w]here a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of individual instances arising under that statute is of no consequence." *Lopez*, 514 U.S. at 558 (internal quotation and citation omitted). As *Wickard* itself demonstrates, even where the regulated activity is of an apparent commercial character, the aggregation principle extends only to the activities of other "similarly situated" individuals. 317 U.S. at 128.

Here, Respondents' activity falls within a traditional area of State regulation, is defined and delimited by State law, and is distinguishable from non-medical use of marijuana on multiple grounds (including that the use is pursuant to a physician's recommendation and does not involve any purchase, sale, or distribution). Accordingly, even if Respondents' activities could be considered together with those of other similarly-situated patients who use locally cultivated cannabis for medical reasons, *Wickard*'s aggregation principle does not justify lumping Respondents together with all individuals who possess, manufacture, or distribute any controlled substance in any circumstances.

d. In *Lopez* and *Morrison*, this Court recognized that an overbroad interpretation of the Commerce Clause undermines the principle of State sovereignty protected by the Tenth Amendment. *See Lopez*, 514 U.S. at 564 (rejecting federal government's Commerce Clause theories because they would extend federal power to "areas where States have historically been sovereign"); *id.* at 567 (Kennedy, J., concurring) ("Were the Federal Government to take over the regulation of entire areas of traditional state concern, areas having nothing to do with the regulation of commercial activities, the boundaries between the spheres of federal and state authority would blur and political responsibility would become illusory."); *Morrison*, 529 U.S. at 618 (noting that the Violence Against Women Act involved "the police power, which the Founders denied the National Government and reposed in the States").

Under the Tenth Amendment, the States retain "broad police powers" to regulate "the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977). Indeed, "direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925). California has exercised its police powers by enacting the Compassionate Use Act, and other States are following a similar path. *See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social experiments without risk to the rest of the country."). Because application of the CSA to Respondents would interfere with the State's exercise of its broad police powers, the entry of a preliminary injunction is also supported by principles of State sovereignty protected by the Tenth Amendment.

e. Petitioners assert that the preliminary injunction "seriously undermines Congress's comprehensive scheme for

the regulation of dangerous drugs" and "threatens a substantial increase in the level of prohibited drug activity." Pet. 9-10, 21. In the courts below, Petitioners had an opportunity to make a factual showing that a preliminary injunction would cause irreparable harm. Petitioners submitted *no* affidavits, declarations, or other evidence in opposition to the motion for a preliminary injunction. Both courts below found that the balance of hardships tips sharply in favor of Respondents. This Court accords a very high degree of deference to such factual determinations, especially when the party challenging the findings offered no evidence to the contrary. *See Exxon Co., U.S.A. v. Sofec, Inc.*, 517 U.S. 830, 841 (1996).

Contrary to Petitioners' assertion (Pet. 15), the court of appeals' preliminary injunction does not authorize Respondents to "function essentially as unregulated and unsupervised drug manufacturers and pharmacies," because California regulates access to cannabis for medical use. Under California law, Respondents are authorized to possess and cultivate only small amounts of cannabis, solely for the patients' medical use, and solely upon the recommendations of their physicians.

Similarly, Petitioners have made no factual showing that the preliminary injunction "threatens a substantial increase in the level of prohibited drug activity." Pet. 21. The States must be trusted to enforce their laws, and they appear to be doing exactly that.[16] In addition, California recently enacted

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[16] *See, e.g.*, Office of the Attorney General, State of California, *Attorney General Lockyer Issues Statement on Federal Threat to Cut State's Share of Anti-Drug Funds* (May 21, 2003), http://caag.state.ca.us/newsalerts/2003/03-062.htm ("Our CAMP program has continued to break records every year in the amount of marijuana seized. Since 1999, we have seized more than 1.25 million illegal marijuana plants worth more than $4 billion."); *State of Washington v. Shepherd*, 41 P.3d 1235, 1238-39 (continued...)

legislation directing the California Attorney General to "develop and adopt appropriate guidelines to ensure the security and nondiversion of marijuana grown for medical use by patients qualified under the Compassionate Use Act of 1996." Cal. Health & Safety Code § 11362.81 (West Supp. 2004).

Ultimately, Petitioners are reduced to arguing that the federal government is being irreparably harmed because the court of appeals has asked the parties to submit briefs in two other pending appeals, one involving cannabis "clubs" and another involving a cannabis "collective," addressing the effect of the ruling in this case, and because the decision in this case has been cited by the parties in three pending district court cases. Pet. at 23-24 & n.6. The short answer to this argument is that such routine litigation developments in other cases presenting different facts do not rise to the level of a "significant adverse impact" (Pet. 22) on the government in *this* case, sufficient to tip the balance of hardships in Petitioners' favor.[17]

3. Respondents may defend the decision of the lower court "on any ground properly raised below whether or not

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(Wash. Ct. App. 2002) (affirming conviction for felony marijuana possession because defendant, who claimed he was "designated primary caregiver" for patient, did not comply with Washington Medical Use of Marijuana Act's requirements; KATU News, *Medical marijuana leader convicted of drug charges* (June 9, 2003), http://www.katu.com/news/story.asp?ID=58243 (Oregon defendant sentenced to three-and-a-half year term for possessing 37 cannabis plants and over one pound of dried marijuana at his home, in violation of Oregon medical cannabis law limit of seven plants or seven ounces of dried cannabis).

[17] Respondents are aware of only one judicial decision applying the court of appeals' ruling in this case, and in that case the district court emphasized that the evidence shows the parties "do not purchase, sell, or otherwise distribute marijuana." *County of Santa Cruz v. Ashcroft*, No. 03-CV-01802-JF, 2004 WL 868197 at *1 (N.D. Cal. Apr. 21, 2004).

that ground was relied upon, rejected, or even considered by the District Court or the Court of Appeals." *Washington v. Yakima Indian Nation*, 439 U.S. 463, 476 n.20 (1979). In the courts below, Respondents raised several additional grounds in support of a preliminary injunction.[18]

a. Respondents have raised a non-constitutional claim based on the doctrine of medical necessity as an implied exemption to the CSA. This Court avoids deciding constitutional issues when it is fairly possible to do so. *See Jones v. United States*, 529 U.S. 848, 857, 859 (2000) (avoiding "grave and doubtful constitutional questions" under the Commerce Clause by construing a federal statute so as not to permit federal officials to reach into "a dwelling place used for everyday family living"); *Ashwander v. TVA*, 297 U.S. 288, 345-48 (1936) (Brandeis, J., concurring).

In *OCBC*, a case involving a medical cannabis cooperative, the Court held that medical necessity is not a defense to manufacturing and distributing cannabis. 532 U.S. at 494 ("[W]e hold that medical necessity is not a defense to *manufacturing and distributing* marijuana.") (emphasis added). In a separate opinion, Justice Stevens, joined by Justices Souter and Ginsburg, emphasized that "whether the defense might be available to a seriously ill patient for whom there is no alternative means of avoiding starvation or extraordinary suffering is a difficult question that [was] not presented" in *OCBC*. *Id.* at 501. In this case, which could result in starvation, extraordinary suffering, and

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[18] The argument for considering the additional grounds raised by Respondents is strengthened by the possibility that a majority of the members of this Court could conclude that Respondents are entitled to relief even if they could not agree on a single rationale for the result. *See, e.g., Welsh v. United States*, 398 U.S. 333, 335, 345 (1970).

even death, the Court should address the "difficult question" that was not presented in *OCBC*.[19]

b. This Court has held "[i]n a long line of cases," that the Due Process Clause of the Fifth Amendment protects certain fundamental rights and liberties. *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997). *See also Lawrence v. Texas*, 123 S. Ct. 2472, 2475 (2003) ("[l]iberty protects the person from unwarranted government intrusions into a dwelling" and "presumes an autonomy of self that includes . . . certain intimate conduct"). The constitutional protection of unenumerated but fundamental rights draws additional support from the Ninth Amendment, which states that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." U.S. Const. amend. IX.

This case implicates perhaps the most fundamental right of all, the right to preserve one's life. *See* App., *infra*, 4a-5a ("It could very well be fatal for Angel to forego cannabis treatment."). It also implicates the fundamental right to alleviate unnecessary pain and agony and protect bodily integrity. In *Glucksberg*, five Justices indicated that these rights may well be entitled to constitutional protection. *See Glucksberg*, 521 U.S. at 736-37 (opinion of O'Connor, J.) (noting that, under the laws at issue in *Glucksberg*, "[a] patient who is suffering from a terminal illness and who is

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[19] The Court's opinion in *OCBC* states, in dicta in a footnote, that "nothing in our analysis suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act." *Id.* at 494 n.7. Of course, this Court is not bound by dicta in its prior opinions. In this case, where Respondents face the prospect of severe pain, suffering and death, the Court should consider the medical necessity issue identified by the concurring opinion in *OCBC*.

experiencing great pain has no legal barriers to obtaining medication, from qualified physicians to alleviate that suffering"); *id.* at 789 (Ginsburg, J., concurring) (agreeing with Justice O'Connor); *id.* at 745 (opinion of Stevens, J.) ("Avoiding intolerable pain and . . . agony is certainly [a]t the heart of [the] liberty to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life."); *id.* at 777 (opinion of Souter, J.) (the "liberty interest in bodily integrity" includes "a right to determine what shall be done with his own body in relation to his medical needs"); *id.* at 790 (opinion of Breyer, J.) (Due Process Clause may protect right to "personal control over the manner of death, professional medical assistance, and the avoidance of unnecessary and severe physical suffering – combined").

The activities at issue here involve some of "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy." *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 851 (1992). To deny patients access to medication recommended by their physicians and necessary to relieve their excruciating pain and extend their lives would "demean their existence" and "control their destiny." *Lawrence*, 123 S. Ct. at 2483. This type of "suffering is too intimate and personal for the [federal government] to insist . . . upon its own vision." *Casey*, 505 U.S. at 853.[20]

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[20] In *United States v. Rutherford*, 442 U.S. 544, 552 (1979), the Court held that the Federal Food, Drug and Cosmetic Act contains "no implicit exemption for drugs used by the terminally ill," and therefore the court of appeals should not have "directed the FDA to promulgate regulations" permitting the drug laetrile to be marketed in commerce to terminally-ill cancer patients. *Id.* at 551. The Court did not decide any constitutional issue in *Rutherford*. In this case, moreover, unlike in *Rutherford*, Respondents are not seeking to require the federal government to take (continued...)

There is no longstanding history in this country of laws directed at medical use of cannabis. Medical use of cannabis was not illegal under federal law until the CSA was enacted in 1970.[21] In any event, "'[h]istory and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry.'" *Lawrence*, 123 S. Ct. at 2480 (quoting *County of Sacramento v. Lewis*, 523 U.S. 833, 857 (1998) (Kennedy, J., concurring)). In addition, in *Lawrence* this Court rejected the fundamental rights analysis of *Bowers v. Hardwick*, 478 U.S. 186 (1986), and protected the "liberty" of the persons involved to engage in the conduct at issue without ever finding that the liberty in question was fundamental.

Current practices, particularly those authorized by an increasing number of States, are also significant. *See id.* at 2480. *See also supra* note 1. As the States consider and act on a variety of measures intended to protect their citizens' "interest in obtaining relief from the suffering that they may experience in the last days of their lives," the "challenging task of crafting appropriate procedures for safeguarding [their citizens'] liberty interests" should be "entrusted to the 'laboratory' of the States . . . in the first instance."

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any affirmative action. Respondents are seeking instead the right to treat themselves with State-approved, physician-recommended medication that they or their caregivers produce for themselves.

[21] *See* Richard J. Bonnie & Charles H. Whitebread, *The Forbidden Fruit and the Tree of Knowledge: An Inquiry into the Legal History of American Marijuana Prohibition*, 56 Va. L. Rev. 971, 1161, 1165 (1970). Under the federal Marihuana Tax Act of 1937, persons could legally obtain marijuana if they paid a transfer tax ($1 per ounce if they registered with the Internal Revenue Service, $100 per ounce if they did not). *Id.* at 1060, 1084 n.6. No State criminalized marijuana possession until Utah did so in 1915, and the 22 States that banned marijuana by the 1930s exempted medical use. *Id.* at 971, 1010, 1027.

Glucksberg, 521 U.S. at 737 (O'Connor, J., concurring) (internal quotation marks omitted).

CONCLUSION

The Petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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June 2004

APPENDIX

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANGEL McCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, and JOHN DOE NUMBER TWO,

Plaintiffs,

v.

JOHN ASHCROFT, as United States Attorney General, and ASA HUTCHINSON, as Administrator of the Drug Enforcement Administration,

Defendants.

DECLARATION OF FRANK HENRY LUCIDO, M.D. IN SUPPORT OF PRELIMINARY INJUNCTION

I, Frank Henry Lucido, M.D., declare as follows:

1. I am a physician licensed to practice medicine in California. I am Board Certified in Family Practice, and have been practicing general Family Medicine at 2300 Durant Avenue, Berkeley, California, since 1979. I have been on the Active Medical Staff of Alta Bates Hospital for over 20 years. I have also been the medical director of skilled nursing facilities. I have been Chairman of the Alta Bates Hospital Medical Education Committee, and a member of the Ethics Committee and the Family Practice Advisory Board. I was voted "Best Doctor in Berkeley" by the Daily Californian newspaper in 1993. Attached hereto is my Curriculum Vitae.

2. I am Angel McClary Raich's primary care physician, and have been coordinating her care with numerous medical specialists. Angel presents a complex and complicated set of conditions. It is my opinion that Angel cannot be without cannabis as medicine because of the precipitous medical deterioration that would quickly develop.

3. Angel is seriously ill. Her medical records confirm that she has numerous serious medical conditions, including life-threatening weight loss, nausea, severe chronic pain (from scoliosis, temporomandibular joint dysfunction and bruxism, endometriosis, headache, rotator cuff syndrome, uterine fibroid tumor causing severe dysmenorrhea, chronic pain combined with an episode of paralysis that confined her to a wheelchair), post-traumatic stress disorder, non-epileptic seizures, fibromyalgia, inoperable brain tumor (probable meningioma or Schwannoma), paralysis on at least one occasion (the diagnosis of multiple sclerosis has been considered), multiple chemical sensitivities, allergies, and asthma, and her body reacts with violent side effects to almost all pharmaceutical medications.

4. Angel will suffer imminent harm without access to cannabis. Chronic severe pain constitutes harm. Nausea and anorexia resulting in weight loss, risking malnutrition, cachexia, starvation, and death, constitute harm. Untreated seizures constitute harm. Post-traumatic stress disorder, inadequately treated, constitutes harm. Angel needs to medicate every two waking hours. If she misses a treatment, it could quickly have dangerous repercussions for her health. She clearly loses weight, and would risk wasting syndrome and death, without cannabis. No one knows why she can't hold onto her weight. Angel could become gravely ill if she loses too much more weight. Angel becomes debilitated from severe chronic pain. The pain is bad enough even with cannabis, but it flares up immediately and becomes unmanageable without cannabis.

5. There are several studies concluding that cannabinoids may have significant anti-tumor activity. I feel that Angel should continue medicating with cannabis in the hope that, among its other benefits, it will prevent her brain tumor from growing.

6. Cannabis works well for Angel in a way that no other medicine has or can be expected to in order to alleviate Angel's medical conditions or symptoms associated with them.

7. Angel has no reasonable legal alternative to cannabis for the effective treatment or alleviation of her medical conditions or symptoms associated with the medical conditions because she has tried essentially all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects. Angel has tried all of the following medications, which all resulted in unacceptable adverse side effects:

Marinol
Demulen Tablets
Codeine
Tylenol #3
Erythromycin
Acetaminophen with Codeine
Serzone
Amitriptyline
Clonidine
Meclizine
Promethazine
Depakote
Prazosin
Carbamazepine
Imipramine
Trazodone
Methadone
Hydrocodone

Dicloxacillin
Chlorpheniramine/Phenylpropanolamine
Beclonmethasone
Vicodin
Dilantin
Tagretol
Desipramine
Valproic Acid
Seldane
Lorazepam
Paxil
Lamotrigine (Lamictal)
Elavil
Soma
Albuterol Solution
Fentanyl
Versed

Most of the medicines listed above, and others not even listed, make Angel vomit violently. Other side effects of the above medications include hot and cold flashes, shakes, diaphorasis, itching, nausea, and drowsiness. In addition, Marinol caused rapid heart palpitations, dizziness, shaking, and insomnia. Diagnostic lumbar tap and sympathetic block and stellate ganglion block in the throat have been performed with no lasting benefit. After a certain number of medications have been tried, it would be malpractice to subject the patient to further unnecessary harm.

8. Angel's medical records confirm that she uses two and one-half ounces of cannabis per week, in various forms, including oral ingestion, smoking, vaporizing, and topical application. There are no other treatments that I can reasonably recommend for Angel, other than what we are already doing in her course of treatment. It could very well

be fatal for Angel to forego cannabis treatments because of a law that may purport to prohibit the medical use of cannabis.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on this 29th day of October, 2002, in Oakland, California.

/s/ FRANK H. LUCIDO, M.D.
FRANK H. LUCIDO, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANGEL McCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, and JOHN DOE NUMBER TWO,

Plaintiffs,

v.

JOHN ASHCROFT, as United States Attorney General, and ASA HUTCHINSON, as Administrator of the Drug Enforcement Administration,

Defendants.

DECLARATION OF DR. JOHN ROSE IN SUPPORT OF PRELIMINARY INJUNCTION

I, John Rose, declare as follows:

1. I am a medical doctor, duly licensed to practice in the State of California, and have been so for 29 years. My practice is located at Brownsville and Yuba City, California. My practice consists of general family medicine. I am a board certified specialist in Family Practice. I am on the Medical Staff of Fremont and Rideout Hospitals. I am also Vice-President of Sutter North Medical Group. Attached hereto is my Curriculum Vitae.

2. I have been the personal physician and family doctor for Diane Monson for nine years and am completely familiar with her medical condition over those years. I have coordinated her care with various other medical practitioners.

3. As indicated from her medical records, Diane suffers from a number of medical conditions. She has degenerative disease of the spine. As a result of her medical

condition, Diane Monson suffers from Chronic Back Pain and Spasms.

4. In 1999, pursuant to California State law, medical cannabis was recommended for Diane as treatment of her medical conditions, including her Chronic Back Pain and Spasms. I have determined that Diane Monson's health benefits from such a recommendation, that medical cannabis use is deemed appropriate for Diane Monson, and that medical cannabis provides necessary relief for Diane's pain and suffering.

5. Although Diane has tried other medical alternatives to medical cannabis, including Flexeril, a muscle relaxant, and Feldene, a powerful anti-inflammatory, those prescription drugs have proven to be either ineffective in relieving Diane's pain and suffering or produce intolerable side effects. In addition, these prescription medications have long term effects that may prove to be harmful to Diane's physical well-being.

6. I have also prescribed Vicodin and Vioxx to attempt to alleviate Diane's pain and suffering. Yet, Vicodin, an addictive drug, seems to have a nauseating effect upon her and I have recommended that she avoid it because of the extremely sick stomach that it leaves her with for several days after any use. In addition, Vioxx, although it appears to relieve Diane's inflammation associated with her back pain, does not relieve her painful spasms.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on this 29th day of October, 2002, in Brownsville, California.

/s/ JOHN B. ROSE, M.D.
JOHN B. ROSE, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANGEL McCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, and JOHN DOE NUMBER TWO,

Plaintiffs,

v.

JOHN ASHCROFT, as United States Attorney General, and ASA HUTCHINSON, as Administrator of the Drug Enforcement Administration,

Defendants.

DECLARATION OF DIANE MONSON IN SUPPORT OF PRELIMINARY INJUNCTION

I, Diane Monson, declare as follows:

1. I am 45 years old and for last 24 years I have lived in the city of Oroville, located in Butte County, California. I am one of the Plaintiffs in the above-entitled action.

2. I am a medical cannabis patient, and have been since March of 1999. I use medical cannabis on the recommendation of my physicians for the treatment of my Severe Chronic Back Pain and Spasms, which have plagued me since 1989. Dr. Rose has been my personal physician for many years and is completely familiar with my medical condition.

3. The constant spasms with which I suffer, and which are related to, and caused by, my chronic back pain, are an extremely painful experience in their own right, comparable in intensity to an uncontrollable cramp.

Cannabis completely eliminates these spasms as no other substance has been able to do. Without cannabis, these spasms would be torturous and unbearable no matter whatever other medications were available.

4. I have tried numerous prescription and non-prescription drugs for my Severe Chronic Pain and Spasms, including Flexeril, a muscle relaxant, and Feldene, a powerful anti-inflammatory. From the beginning those drugs caused me significant problems. Flexeril has a very powerful effect on me and makes me groggy in any amounts, even if I halve the recommended dosage. If I take the prescribed dosage, I inevitably fall asleep and am unable to function as a normal human being. Flexeril has been ineffective in relieving my spasms and also has many undesirable side effects. In addition, I am quite concerned about its effect on my organs, including my kidneys and liver, over the many decades of necessary use, even if it were effective in relieving my pain.

5. The other drugs I have had prescribed over the years are Vicodin and Vioxx. Vicodin, an addictive drug, has a complete nauseating effect upon me and I avoid it because of the extremely sick stomach that it leaves me with for several days after any use. Vioxx is supposed to be easier on the stomach, so I take it occasionally to reduce the inflammation associated with the back pain. Regardless, it does not relieve the spasms.

6. I am employed as the office manager for one business and the bookkeeper for several other businesses as well. Inevitably, the stress levels with these responsibilities rise throughout the day. The more stress I have, the worse the back pain is. I have sought out various methods of self-help in dealing with my pain and suffering, including exercises, long walks, yoga and stretches, which I do each and every night. I am keeping my weight down and eat a healthy diet. I walk a very hard mile and a half per day,

which helps to strengthen the back muscles as well. Regardless of this regimen, my chronic back pain and spasms generally start by late morning each day; when the yoga and walking that I do earlier that day wear off. From that point in the day forward the pain worsens by the hour. Before I began using medical cannabis I was having back spasms multiple times per week. Once a spasm starts it is very difficult to relax my back enough to make it stop. Generally speaking, work is impossible during spasms, sitting down is impossible, and the only way to even partially relieve the severe pain it causes is to lie down altogether.

7. In early 1999, when I first tried cannabis for my back pain and spasms, I immediately noticed a massive improvement in my level of pain. And from the moment I began to use medical cannabis my spasms decreased in frequency about 75 percent. The medicine relaxes me without making me sleepy, and so I can work again without pain. I still do most of the self-help things I have been doing for years, and now I have added medical cannabis to my self-help list. In addition to the smoking method, I use a vaporizer for the cannabis. My physicians recommended the vaporizer. Another delivery method I have used with cannabis is a sublingual spray form. This is a method I use in a more crowded situation, where other people might object to the smoke from my medicine.

8. In early 2002 I elected to stop hormone replacement therapy. I had taken HRT for nearly 14 years at that time and I began to worry about the side effects of that medicine and the recently reported risks associated with such use. But I had no idea of the effect that quitting would have upon my body and my psyche. The physical symptoms were fairly intense, with hot flashes and trembling hands. The mental repercussions were even more debilitating. I became anxious and had a hard time concentrating. Tears would come easily for little to no reason. Although I have always sought out new clients and work, I was overwhelmed by

responsibilities and sought no further clients. I have to say my self-confidence plummeted in those first few months after ending my hormone replacement therapy. I then discovered that cannabis helped me through this stage in my life, too. While contemporaries are being prescribed Paxil and Prozac and other drugs to help with these menopausal symptoms I rely on cannabis to calm my psyche and alleviate the symptoms. Its effect upon me is soothing and I find that cannabis alleviates the physical symptoms as well.

9. With regard to all of the above symptoms and medical conditions, I have found medical cannabis to be both effective and free of undesirable side-effects. Cannabis virtually eliminates my debilitating and extremely painful Spasms and greatly relieves my Chronic Back Pain. Without cannabis, my spasms would return and I would be subjected to intense pain that cannot be relieved any other way. I have tried various combinations of prescription pharmaceutical medications, but they are often ineffective and they always disrupt my quality of life by interfering with my ability to function.

10. On August 15, 2002, deputies from the Butte County Sheriff's Department and DEA agents visited our home. After a discussion with them, the sheriff's deputies agreed that my cultivation and possession of six cannabis plants was lawful under the Compassionate Use Act of the State of California. The DEA agents insisted on seizing and destroying my plants. For three hours we talked with them, reasoned with them, and finally pleaded with them to leave the plants alone. The local District Attorney, Mike Ramsey, also fought for my right to keep my medicine by calling John K. Vincent, the U.S. Attorney for the Eastern District of California, to plead with him to keep the DEA agents from destroying my medicine. All of the efforts by my local law enforcement agents and the Butte County District Attorney were to no avail. As I stood and watched, the DEA agents chopped down my medicinal plants. I was crying and my

back begun to tighten up; for the rest of the week I experienced debilitating back spasms. I have not had a good night's sleep since the actions of the DEA in destroying my plants. My 20-year marriage is suffering as well because my wonderful husband also has to deal with all the repercussions of this action. We do not feel safe; we have had our civil rights and our rights under California law taken from us in our own back yard. I must now find a way to get my medicine from another source. To do so will be very expensive and I will have no idea what the quality of the medicine I receive will be.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on this 29th day of October, 2002, in Oroville, California.

/s/ DIANE MONSON
DIANE MONSON

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANGEL McCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, and JOHN DOE NUMBER TWO,

Plaintiffs,

v.

JOHN ASHCROFT, as United States Attorney General, and ASA HUTCHINSON, as Administrator of the Drug Enforcement Administration,

Defendants.

DECLARATION OF ANGEL McCLARY RAICH IN SUPPORT OF PRELIMINARY INJUNCTION

I, Angel McClary Raich, declare as follows:

1. *Background:* I am a "medical necessity" medical cannabis patient. My medical records show I run a very real risk of malnutrition and starvation without the use of medical cannabis. I would starve to death without cannabis. I have been diagnosed with more than ten serious medical conditions including an inoperable Brain tumor, life-threatening wasting syndrome with severe weight loss borderline cachexia, a Seizure Disorder, Nausea, several Severe Chronic Pain Disorders, including Scoliosis, Temporomandibular Joint Dysfunction Syndrome, Bruxism, Endometriosis, a Tumor in my Uterus, and other documented medical conditions. My medical conditions are very complicated, complex, and difficult to manage. I am blessed to have a great primary care doctor and many dedicated specialists and extensive medical records. I have been permanently disabled since September 1995. I am a mother

of two children. My son is 16 and my daughter is 14 years old.

2. I have been using cannabis as a medication for about five years, every two waking hours, every day, and I have not been adversely effected by my medical use of cannabis -- just the opposite. On a good day if you were to see me face to face you may not even know I am disabled. I do not enjoy being disabled nor do I like taking medication every two hours, but I have no alternative. Medical cannabis keeps me alive and greatly reduces my suffering. I can not use Marinol pills; because of my extreme drug sensitivity, I am just not able to take them. Only the natural cannabis plant works for me.

3. I was in a wheelchair from January 1996 to August 1999 because of my many medical conditions and their debilitating effects on my body. In 1997 before the use of cannabis I was debilitating quite fast. All of my doctors were not getting anywhere with my treatment and nothing seemed to work, but by August of 1999 I was walking again because of medical cannabis. Cannabis was responsible for getting me out of my wheelchair and restoring my mobility on the whole right side of my body.

4. I had complications taking nearly every type of synthetic medication my doctors prescribed. Practically every single medication my doctors gave me would make me extremely ill, causing me to vomit violently, sometimes for 24 hours. I had allergic reactions and chemical sensitivities to nearly all of the medications my doctors prescribed. For example, I am allergic to all narcotics and opiates. When I take any narcotic or any opiate, within about 20 minutes I am on the floor with my face in a pan or small trash can violently vomiting, I get the shakes, hot and cold flashes, and insane itching that nothing can stop. Being partially paralyzed on the floor, it was Hell. I could not hold myself up. I

sometimes needed someone to hold up my head while I was vomiting. I was simply too weak to move.

5. By 1997 my doctors told me I would never walk again and that they could not control my pain. My medical conditions were triggering each other as I became increasingly worse. That is when my doctors and I started talking about medical cannabis as a medication to help alleviate my pain and suffering.

6. My specialists do not know why I can not hold onto my weight. In 2000, my wasting syndrome was out of control, becoming life-threatening and causing my weight to drop to only 94 pounds. My health -- even my life -- was at great risk. My doctor worked quickly to raise the levels of cannabis in my bloodstream. Every time my level of cannabis drops, I can lose as much as one pound per day. My doctor says I must never be without cannabis treatments. I will always have to fight to keep my weight balanced; however, without cannabis it would make that fight impossible.

7. I suffer greatly from pain every single day. The prolonged pain and suffering from my medical conditions significantly interferes with my quality of life. I have not been pain-free for several years, but at least I am not in a wheelchair anymore thanks to medical cannabis. My experience is that cannabis allows me to combat all of my diseases daily and gives me the strength I need to fight to stay alive.

8. The hardest part of being disabled is watching the suffering in your children's eyes as they watch you endure such suffering with no end in sight. They experienced great joy knowing that cannabis was responsible for giving their mommy back to them. Cannabis saved my life and gave my children their mother back. I would rather use cannabis to end the suffering from my conditions, and be alive, than to

suffer endlessly while I die knowing that there *is* something that could help treat my conditions.

9. It may be difficult for the reader to comprehend the amount of intense pain and suffering described herein. When you become disabled one of the most difficult things is accepting that you are disabled and life as you knew it has ceased to exist. Your life changes forever from that moment on. When you are told you are *permanently* disabled it is even worse. Being permanently disabled has been very difficult for me to deal with, day in and day out, year after year. It is equally difficult for my family. As I fight to stay alive every day, my biggest challenge on a daily basis is combating my diseases, trying to minimize my suffering, and at the same time doing my best not to go into "overload" from excruciating pain. I do the best I can while remembering to have compassion for all life, and keeping my dignity and my grace. I am finding it a challenge to have compassion for the United State Government, when the Government wants to sentence me to death for being disabled and fighting to use a plant that is saving my life. I am weak and weary and afraid of being raided, and I am afraid of what my death would do to my children and my husband. I am afraid of being tortured by being denied cannabis, and I am afraid of the excruciating pain that would cripple me while being forced to starve to death.

10. The Drug Enforcement Administration (DEA) is attacking sick, disabled, and dying Americans. Since September 11, 2001, the DEA has continued raids on the California medical cannabis community. The DEA has been terrorizing and doing harm to other patients using cannabis. This is creating great fear for me and my children. I am just fighting for my life. I promised my children I would fight to stay alive and I am not about to go back on that promise.

My Medical Conditions, Symptoms, and the Stories Behind My Suffering:

11. I will do my best to explain all of my complicated medical conditions starting in my childhood. The time period between 1995 and 1999 is the most difficult and is very painful to explain. All of my doctors knew I was seriously ill and suffering from severe pain. The doctors became frustrated because they could not figure out what was happening to the right side of my body. My doctors kept changing my diagnoses while trying to unlock the mysteries to why my health was failing, only to end up with more questions than answers. Many doctors told me that I was too complicated for them to understand, that they could no longer help me, and then referred me to another doctor. I had too many medical conditions affecting me the same time.

12. *Post Traumatic Stress Disorder (P.T.S.D.):* From the age of four years old to when I was in the six grade my grandfather repeatedly molested, threatened, imprisoned, and tortured me. My doctors say that my grandfather was one of the worst child molesters on their rating scale. My grandfather was just below the child molesters that kill children. I was physically and mentally abused by other family members throughout my lifetime. I have worked very hard throughout my life to heal my wounds by getting the help I needed, and by being a good mother and a good citizen who obeys the laws. It was a long road, and I fought hard to keep abusers out of my life. I was diagnosed with P.T.S.D. in 1987.

13. Since the Federal Government escalated its raids on California medical cannabis patients, I have been experiencing more intense P.T.S.D. symptoms. I find myself overwhelmed feeling suddenly in danger, and I have become consumed with feelings of fear, helplessness, and horror. The constant threat I feel is making me re-experience my past traumas. It is causing me to feel the same mental, emotional, and physical experiences that occurred during the past traumas. This includes thinking about my past trauma and the threat of losing my life. For the past year I have been

experiencing the following symptoms due to the threats and attacks from the United States of America's war against cannabis patients: I get bad dreams and nightmares of being attacked and killed by the federal government. I am also having flashbacks and nightmares of being unsafe and unprotected. Every time another patient or provider is raided, I am overwhelmed with anxiety and fear of being in danger, wondering if I will be the next patient to be attacked. I am deeply concerned about my own health and safety. I become increasingly more upset every time I am reminded about the trauma we patients face at the hands of our own federal government. I get real angry and aggressive feelings because I feel that I have to defend myself before the federal government breaks in my door, attacks me, incarcerates me, and kills me. My brain can not handle any kind of trauma. I feel the trauma is happening again, only now it is the federal government abusing me. I feel as if I am in danger. I experience sensations of panic, and trying to escape, and of thinking about attacking first, yet I am too sick and my body is too weak. These experiences are not voluntary; no matter how hard I try, I usually can not control them or stop them from happening. I am just as innocent now as I was when I was a child because I am sick, disabled, and fighting to stay alive. I had my P.T.S.D. symptoms pretty much under control until the federal government started escalating its raids against California cannabis patients. Cannabis helps keep me from living in my past, helps me deal with flashbacks, and helps me cope with the P.T.S.D. symptoms being brought on by the federal government's actions against medical patients. It helps me have the courage to face my past abuse, the feelings of never being safe or protected by anyone, my anger, my sadness, and my hurt in a calm safe manner. Cannabis allows me to cope, and manage my P.T.S.D. symptoms.

14. *Scoliosis:* Scoliosis is a curvature of the spine. My first diagnosed medical condition was Scoliosis. I was in

the seventh grade when it was diagnosed. The doctor said my back is shaped as a backwards "S" and my spine is twisted and rotated. The doctor said that if my spine were rotated two more degrees he would have had to do surgery and put a steal rod into my back, but instead I had to wear a back brace for three years. This was my first experience with chronic pain. The chronic pain in my back has never gone away, still to this day. In fact, as the years go by the chronic burning pain has become more intense and more difficult to tolerate. I experience burning pain in my back muscles and around my vertebrae. I learned at a young age how difficult it can be to be a handicapped person and how mean people can be to the disabled. While I was wearing my back brace children and adults made fun of me. I lost all of my friends, and no one wanted to hang around me anymore, just because I was in a back brace. It made my seventh through ninth grade years of school very lonely. I was not able to do much of anything; I was hurt, embarrassed, and in chronic pain. I could not even turn my head because the brace came up under my chin and went down to my tale bone. The brace was very painful. I remember crying all the time.

15. For years, my scoliosis has given me prolonged chronic pain in my spine that interferes with my quality of life. It also affects my mobility daily. One part of my spine is constantly moving, making loud painful cracking noises. Another part of my spine locks up, which is extremely painful. When this happens my neck, jaw, collar bone, shoulder, and rib cage lock-up tight, preventing me from moving freely and creating an unstable body structure. In that condition moving my body creates severe chronic pain and excruciating chronic burning pain in my neck, jaw, back and sides, ribs, and down my right arm. Staying still is equally painful. Without cannabis my tendons, and ligaments feel like an over-stretched rubber band about ready to snap. Cannabis makes my muscles, tendons, and ligaments more pliable, allowing my body to move and go

about my daily life. Cannabis allows me to cope with the severe chronic pain and burning every movement brings to my body. I notice a big difference when eating cannabis before going to physical therapy, it helps relax my muscles, making it easier for my physical therapist to help relieve some of the pain and burning and unlock my vertebrae and my other joints.

16. *Endometriosis:* Endometriosis come from the word "endometrium," which is the tissue that lines the inside of the uterus and builds up and sheds each month in the menstrual cycle. In Endometriosis, tissue like the endometrium is found outside the uterus, in other areas of the body. These growths cause disabling chronic pain, scar tissue, and other problems. Just before I turned sixteen years old I was diagnosed with endometriosis and my doctor told me to go home, pack a bag, and meet him at the hospital because they had to do surgery. My endometriosis was out of control. I was in excruciating pain and the cramps made it hard to move around. During the first two days of my period each month I was not be able to move at all. I had to stay down. I would curl up in a tight ball and cry for hours. In my second surgery for endometriosis the doctors not only found the endometriosis, but they also found several cysts. By the time I was 21 years old I had already had three surgeries for endometriosis. Through the years my endometriosis has changed, and the operations become more complicated. Every time they open my stomach up they risk damaging my organs, it makes it more difficult to work around the scar tissue. About every four to five years I must have surgery for endometriosis and scar tissue. I can always tell when it is time for surgery because my periods become overloaded with pain, I am no longer able to move around, and I can't move my legs to walk. I become paralyzed from the excruciating pain and I bleed so heavily that I become light-headed from such fast blood loss. The pain can cause me to have seizures. To date, I have had seven surgeries for

endometriosis, and with six out of the seven I woke up in the recovery room violently vomiting. The drugs made me vomit very violently, sometimes for over 24 hours, and after just having surgery vomiting is extremely painful. In 2001 my pain from endometriosis again became so severe that I was in tears. I had surgery in November 2001. The hospital gave me a room on the oncology floor so I could medicate with cannabis, using my vaporizer in the hospital promptly after coming out of recovery. Most patients after having surgery can have a narcotic or opiate. When I got back to my room after surgery I was so weak, I was not able to prepare my cannabis or my vaporizer. A family member helped me by holding up my vaporizer while I medicated with cannabis. The nurses at the hospital all asked about the medical cannabis and how well it helped my medical conditions, and they wanted to see me vaporize with cannabis. My doctor told me I recovered faster with cannabis than the patients who use narcotics or opiates. The doctors and nurses were all amazed because they got to see how effectively cannabis works right before their eyes.

17. *Rotator Cuff Syndrome:* After my son was born in 1986 I went back to work in a lumber mill where I became seriously injured working at a glue machine. I could not move my right shoulder. I was in tears and in extreme pain and muscle spasms. I was taken to the hospital where I was diagnosed with rotator cuff syndrome. After having it for many years, the chronic burning pain is worse than when I was first injured. I went to therapy for months until I was sent to another specialist who gave me five sessions, of five shots each of cortisone in my right shoulder and my neck. The cortisone helped for about three years, then the excruciating pain returned. My right shoulder never went back to normal. I have problems doing anything repetitive with my right arm, hand, shoulder, or shoulder blade. I suffer from excruciating burning pain, my shoulder freezes up, and I loose the mobility in my shoulder. It is cannabis

that allows me to gain back some of this mobility. Through the years I have also had several injuries to my right shoulder (See paragraph number 18.). Cannabis makes the muscles, tendons, and ligaments around my shoulder joint more pliable, allowing me the use of my right arm. Cannabis allows me to cope with the severe chronic pain and chronic burning associated with rotator cuff syndrome. I noticed a big difference when eating cannabis before going to physical therapy; it helps relax my muscles making it easier for my physical therapist to help relieve some of the chronic pain and burning and unlock my shoulder and my shoulder blade.

18. *Other Past Spinal Injuries:* The year of 1991 was a bad year for me. I was in three accidents in a two month time period. All three accidents injured my spine and the right side of my body. I slipped and fell, injuring my spine on the right side; I was rear-ended by a big truck, injuring my back, neck, pelvic area, and bladder; and then a car hit me while I was walking, injuring the right side of my body again. It was all very painful and my body did not heal as fast as it should have. I had to see a chiropractor and a physical therapist for months. My body is extremely fragile and it does not heal easily, so I do a lot of suffering. Having injury upon injury caused permanent damage to my body structure. I have continued to endure constant chronic pain and chronic burning ever since.

19. *Multiple Chemical Sensitivities, Allergic Reactions, and Asthma:* My treatment is complicated by the fact that I am violently allergic or I have severe multiple chemical sensitivities to almost all pharmaceutical medicines. This interferes with the treatment of all of my medical conditions, and it means my suffering can not be controlled by synthetic medications. This makes it extremely difficult for my doctors effectively to help me combat my diseases. I have problems with asthma and allergies, which make me wheeze and cough from the lack of air. I also have problems with chemicals that are in many skin products, air fresheners,

perfumes, and detergents. I am not able to use pharmaceutical asthma medications and I am not able to take anything for my allergies. I become nauseated from most over-the-counter medications. So I just suffer. All of my doctors including my specialists have been supportive when it comes to my medical use of cannabis. I do not have any other alternative to battle my many complicated and complex medical conditions. Cannabis *is* maintaining my health. I am not just sensitive to synthetic prescriptions, I am also chemically sensitive to things such as chemicals that some cannabis growers use. These additives are not harmful to most patients; I am just extremely sensitive.

20. *Severe Chronic Pain:* Every second I experience chronic pain in varied degrees, ranging from a medium level of pain to a complete overload of pain, brought on by one or a combination of the chronic pain conditions from which I suffer. When I am able to sleep it provides meager escape from the ever present chronic pain I experience. I have to force myself to do everything, including getting out of bed every day. I wake up several times per night and rarely get a restful night's sleep because of the chronic pain. Because I have an extremely high pain threshold, I can occasionally function and still try to go about my life, even in the midst of experiencing pain. On frequent occasions, however, the chronic pain becomes so great that I experience difficulty performing everyday activities, or the chronic pain is so overpowering that I become completely debilitated and cannot get out of bed. Then I am usually down for a few days.

21. When my nervous system becomes too overloaded with pain I experience muscle spasms and seizures. My treatment is complicated by the fact that I am violently allergic to almost all pharmaceutical medicines. Cannabis, however, has the effect of making it easier for me to tolerate my constant chronic pain, although it does not make the pain go away. The efficacy of cannabis is well

established as an analgesic. Cannabis is the only medication that keeps me alive and makes my severe chronic pain more manageable. Without cannabis, my chronic pain would be even more torturous.

22. *Paralysis:* Due to all of the traumatic events in my life, in 1995, one last traumatic event caused my brain shut the whole right side of my body down for years, leaving me in a wheelchair until late 1999. I was barely hanging on because of all the pain and suffering I was forced to endure. It took many years and many doctors to diagnose all of my medical conditions, and I was suffering unexplainable, excruciating pain. My doctors were giving me many different kinds of prescription drugs; these same prescription drugs were making me vomit violently. My health continued to spiral downward, leaving me with no hope at all. Months went by. After feeling that my doctors were not helping me I changed doctors once again. Even though I felt like I was drowning in pain, I kept the promise I made to my children that I would never give up again. I was going to do whatever I had to do, to get well and become healthy, or as healthy as I could be given my medical conditions. A new doctor sent me for a brain MRI in May 1999. It showed I have a one centimeter brain tumor on the left side of my brain, adding yet another physical medical condition. My doctor also sent me for an EEG, which showed I was having seizures. Then my doctor sent me to the Stanford University Hospital Epilepsy Center and a brain tumor specialist. Because I was not able to use the right side of my body and I was having cognitive functioning complications. During this same timeframe I was once again diagnosed with Post Traumatic Stress Disorder.

23. The use of cannabis was responsible for getting me out of my wheelchair. After I began using cannabis in 1997 I started feeling nerve sensations in my body. I stopped using cannabis from off the street in 1998. I started to get better from the medicine I obtained from the Oakland

Cannabis Buyers' Cooperative. The better quality cannabis made all the difference in the world. The sensation slowly started coming back into my right side. I was so happy, I really wanted to walk again. By August 1999 I was able to move my right arm, toes, ankle and my foot. Then I was able to make small movements in my toes and fingers, and eventually I was walking again. Learning to walk again was very difficult and painful. Without cannabis being continually in my body I would surely become wheelchair bound once again; this possibility is very frightening to me and my family.

24. Cannabis has given me faith, hope, happiness, better health, and family. It helps tone down my pain and suffering, not to mention: it keeps me alive. Cannabis proved to be the only medicine that brought back feeling in the right side of my body and got me out of my wheelchair.

25. *Two Demulen Tablets:* In September 1995, three days before I lost feeling from the waist down, I went to a new doctor regarding my severe endometriosis pain and complications. It was really time for me to have surgery again for my endometriosis. The doctor did not want to give me surgery, instead she wanted to put me on birth control pills to control some of the symptoms. I explained to her that I was allergic to all forms of birth control pills. The doctor told me that just because I was allergic to a drug when I was a teenager and in my early twenties did not mean I was still allergic it. I took the pills on the advice of my doctor and I have been paying for that ever since. After taking just two Demulen pills, my health was taken away forever.

26. I became permanently disabled in September of 1995. My chronic pain condition became complex right from the start. I was at work when all of the sudden I felt a strange sensation go down my leg. In a matter of moments, my right leg was like Jell-O, bright red, and cold as ice. I could not walk on my right foot because my ankle was so weak it

would fall to the side. I was taken straight to the doctor. I was quite afraid because I could not feel my body from the waist down on the right side of my body. The next day I was dragging my leg around and I was unable to stand. Fear raced through my body and tears came from my eyes. The severe chronic pain I was experiencing was putting me in a world of pain and suffering, and making my life a living hell and my doctors' jobs extremely difficult when it comes to treating any one of my medical conditions.

27. The chronic pain I was experiencing caused me to become partially paralyzed on the right side of my body from the waist down and I was unable to use my right leg. My scoliosis and my endometriosis made things even worse for me. I did end up having surgery for my endometriosis and scar tissue six weeks after I took the birth control pills. It is extremely difficult for me to battle the physical manifestations of chronic pain and my nervous system is very fragile. I experience complications when my chronic pain conditions trigger each other, which makes all of my symptoms worsen.

28. *Suicide Attempt:* In August of 1997, shortly before I discovered the benefits of medical cannabis, my chronic pain levels were so high for such a prolonged period of time that, my body and soul racked with agony, I attempted suicide - as a desperate attempt to end the excruciating pain and my suffering. I was drowning in chronic pain for years, it was the only escape I could perceive from my torment. The lack of sleep effected my thinking process, until my brain was foggy and I could not see past the excruciating pain. I could not live another day with that kind of chronic pain, which nothing was helping. I was lost, I lost my faith, I lost my will, and I lost any hope I had left. I just could not handle the torture from the chronic pain anymore. I am blessed to be alive today, for I have been given a second chance at life. That night I made a promise with God that I would do God's work if He gave me back my legs, and I

promised to do my best not to complain about the chronic pain if God would helped me find something to help ease the pain. A couple of weeks later, a nurse who had been watching me suffer asked me if I had ever thought about using medical cannabis. I was offended because I was not in support of marijuana use. My doctors could not figure out what had been wrong with me for over two years. At the time I was in a wheelchair and partially paralyzed on the entire right side of my body. I wanted my suffering to end as soon as possible. I was becoming sicker and sicker from the prescription drugs the doctors were pumping into me, only to vomit the pills up prescription after prescription, until the cure was worst than the disease. I felt hopeless and I just wanted my suffering to end.

29. My numerous chronic pain conditions, as will all my medical conditions, present a complicated mosaic of problems with a confusing interplay between each other, exhibiting the potential of a vicious spiral that exacerbates all of my medical conditions. When I first started experiencing extreme levels of chronic pain I did better at hiding my pain and not letting the pain show on my face. Year by year it gets harder and harder to hide the chronic pain my body feels because pain takes over my body. Then there are the days I just can not get out of bed at all except to go to the bathroom. The chronic pain keeps me down until my body stops burning, throbbing, cramping, and my muscle spasms go away. I am tortured by chronic pain of all different kinds. It turns out to be a never ending circle of chronic pain. The chronic burning pain that goes on for days is the worst torture of all. It is hard to wake up every day and thank God for being alive, but I do thank him everyday for giving me back my legs so I can walk. So I will do whatever I have to do to ease this excruciating pain and to fight to stay alive. I have to do it for my children, I have to do it for myself, and I have to do this for my husband. I love them all so much I want to be with them until I die of old age, not because the Federal

Government raids me and puts me in jail where I could experience an even greater debilitating pain while I starve to death.

30. Dealing with high levels of chronic pain everyday for years becomes more and more difficult with each passing year. My body is deteriorating. I am a prisoner of my medical conditions and I am trapped in my body being made to live the rest of my life in severe chronic pain. Is not that enough? I will do whatever it takes to stay alive and as pain free as I can possibly be. When my nervous system becomes too overloaded with pain I experience muscle spasms and seizures.

31. *Muscle Spasms:* I regularly have muscle spasms that stem from my chronic pain. Spasms are sudden, involuntary muscular contractions, either of a single muscle or of a group of muscles. They are often very painful. Cannabis helps relax my muscles, making them more pliable, and it helps release my muscle spasms and cramps, allowing me to function more easily physically.

32. *Chronic Headaches:* I get very bad chronic headaches. They are extremely painful all over my head. The muscles on my head and face can go into spasms, causing excruciating chronic headaches making me find a dark quite place. Sometimes I get a bad headache just before I have a seizure. My headaches come from several of my medical conditions. Nearly every morning when I get up I have a headache. If my headache is not too bad I can get away with just vaporizing or smoking cannabis. When my headaches become overpowering, not even hours of being in a dark quite place helps. The only medication that helps my severe headaches is eating cannabis foods.

33. *Nausea:* I have chronic nausea that interferes with my quality of life. It makes eating and drinking difficult. My nausea can make my wasting conditions worsen when I am just not able to eat. When I eat I become

even more nauseated, which makes forcing myself to eat a real battle. When I first started suffering from nausea my doctors tried me on several anti-nausea medications and a medication that was supposed to help me eat. The medications not only made me more nauseated but they also would make me vomit violently. If the cannabis levels in my bloodstream drop even just a little bit I can become extremely ill. Preventing and controlling nausea helps ensure that I am able to eat food properly. It is hard to eat properly when you feel nauseated all the time and when even the smell, sight, or taste of food can trigger the nausea, making it all worse. Sometimes after eating my stomach will cramp up leaving me in wrenching pain. However, without the use of medical cannabis I would be unable to eat at all and I would not be able to eat enough food to help me hold onto my weight. Cannabis helps moderate my nausea and stomach cramps, and helps me eat and maintain my weight, without adverse side effects.

34. *Severe Temporomandibular Joint Dysfunction Syndrome (TMJ) and Bruxism:* Temporomandibular Joint Dysfunction Syndrome causes facial pain. The temporomandibular joint (TMJ) is a gliding joint in the jaw. The syndrome hinders my jaw from opening and closing, which makes talking and eating difficult. My jaw can become tightly locked closed. When that happens the only way I can open my mouth is to force it open by cracking my temporomandibular joint, which is very painful.

35. Bruxism is forceful grinding and clenching of the teeth usually during sleep. The pressure that is generated across the teeth can be an incredible amount of force. Problems occur as a result of these forces being applied over many years.

36. Temporomandibular Joint Dysfunction Syndrome and Bruxism cause muscle spasms and muscle cramps that create severe chronic pain in my face and jaw

muscles. Due to the Bruxism and TMJ, I am losing the bone and gum support in my mouth, and I am experiencing early periodontal problems. Because of these early periodontal problems, my dentist had to remove teeth in 1997, 1998, and 2001. I have two more teeth that are about to fall out. In effect my teeth have loosened because of the "rocking" back and forth. My bone, gums, and teeth ache and throb all the time and are very sore, and are sensitive to hot and cold. My mouth and jaw hurt all the time. Sometimes in the morning when I wake up I can't move my jaw and I can't chew. My whole face hurts and aches from the muscle spasms and the chronic pain. It becomes difficult to talk when my jaw locks up on me. Nothing helps the chronic pain go away completely. When the muscles in my jaw are overused they become sore and spasm. The spasms even make my neck hurt. I get chronic headaches from having TMJ and Bruxism. Cannabis helps release the muscle cramps and relax my jaw, face, and neck muscles in order for my temporomandibular join to crack so I can slightly open my mouth to eat something soft. Cannabis allows me to cope with the chronic pain and burning in my jaw and neck. Without cannabis being contentiously in my body I would not be able to relax the muscles around my mouth. Without the use of cannabis my TMJ and Bruxism would spin out of control, worsening my life-threatening weight loss, and rapidly causing malnutrition, starvation, and cachexia. For these reasons it is extremely dangerous for me to be without the use of cannabis.

37. *Life-Threatening Weight Loss, Malnutrition, Cachexia, and Starvation:* Since 1998, I have experienced great difficulty maintaining a healthy weight. My physicians, including my gastroenterologist, are unable to diagnose the root cause of my weight problems or to prescribe an effective course of treatment. One fact, however, is clear: I literally cannot eat without a sufficiently high level of cannabis in my system. Without cannabis, my weight can precipitously drop

as much as one pound per day. As a five-foot four-inch tall woman, I dropped from 106 pounds to a dangerously low weight of 93 pounds during the course of four weeks in which I could use cannabis only on two weekends pursuant to a family court order (which was subsequently overruled due to my rapid health failure) in a child custody fight with my children's father. I struggle with Life-Threatening Weight Loss and Wasting Syndrome, a medical condition generally diagnosed as Anorexia/Cachexia meaning loss of appetite and rapid weight loss. (I do *not* have a better-known condition called anorexia nervosa, a psychiatric disease in which patients are obsessed with being thin and have an unrealistic body-image.) My body-image is accurate; I see how thin I am and I work extremely hard everyday to eat enough. I simply cannot eat without the aid of cannabis. I eat between 2500 and 3000 calories per day, yet I have trouble getting my body to gain weight, for reasons that my physicians do not understand. The efficacy of cannabis is well established for stimulating appetite and promoting weight gain. The federal government claims cannabis has no accepted medical use and it claims cannabis is harmful to your health. Cannabis *is* safer than death. Without cannabis, I would run the very real risk of Malnutrition and Starvation. One result of Starvation is death. Dropping weight fast can become critical. Every time I have tried to cut my medical cannabis treatments back my weight dropped immediately. It is then difficult to bring my weight back up. This is how my doctors and I know that I require two and one-half ounces per week (equaling over eight pounds per year). Fighting to keep my weight up every single day is my biggest battle.

38. *Fibromyalgia Syndrome (FMS):* In 1997 I was first diagnosed with fibromyalgia. The symptoms slowly lessened, but then flared up again in early 2002. Fibromyalgia is a widespread musculoskeletal chronic pain and fatigue disorder that is often precipitated by physical trauma. Fibromyalgia means pain in the muscles, ligaments,

and tendons -- the soft tissue in the body. When my fibromyalgia acts up, my body feels extremely fatigued and every single muscle in my body screams out pain. When my body overloads with pain I will be flat on my back for days. The chronic pain keeps me down until my body stops burning, throbbing, cramping, and my muscle spasms go away. The best way I can describe it is "everything hurts". The chronic pain and the stiffness feel like a big diesel truck ran over my body, with the groups of muscles that are frequently used hurting most intensely. I also have neurological symptoms that are associated with FMS and some of my other medical conditions. As mentioned, I get extremely fatigued. The best way I can describe the fatigue is that it is like a "brain fatigue" in which I feel totally drained of energy. It feels as though my arms and legs are tied to concrete blocks, and I have difficulty concentrating. I am unable to focus or make big decisions on the days I am overwhelmed by this brain fog. I have problems falling asleep and staying asleep due to my high levels of pain. Many FMS patients, including myself, have problems with deep levels of sleep. "Stage four" sleep is constantly interrupted by bursts of awake-like brain activity. I spend nights with one foot in sleep and the other one out of it. Other symptoms I have from FMS are premenstrual syndrome, painful periods, chest pain, severe morning stiffness, and cognitive functioning problems. Sometimes I have a numbing feeling in my arms and legs, tingling sensations, muscle twitching, skin sensitivity, dizziness, and impaired coordination. I also have problems with losing my balance and stumbling.

39. Without cannabis my tendons and ligaments feel like an over stretched rubber band about ready to snap. Cannabis makes my muscles, tendons, and ligaments more pliable, allowing my body to move and go about my daily life. Cannabis allows me to cope with the severe chronic pain and chronic burning every movement brings to my

body. I noticed a big difference when eating cannabis food before going to physical therapy; it helps relax my muscles making it easier for my physical therapist to help relieve some of the pain and burning. Without cannabis being continuously in my body I would never be able to tolerate the burning and pain. My chronic pain levels become so high it makes even my skin hurt, making it is very difficult for me mentally to be in my body. Cannabis rescues me from the torture I have to endure from fibromyalgia. When I go to bed at night my whole body may throb like a strong heart beat, making it impossible to fall asleep. Cannabis helps my fibromyalgia symptoms and allows me to have a life with my family.

40. *Non-Epileptic Seizures:* I started having non-epileptic seizures in 1996, though my doctors did not diagnosis the seizures until 1999. When I have a seizure, I can lose awareness, have uncontrollable movements of my arms or legs or both, shake all over, and fall to the ground. Between seizures I experience problems related to memory, language, mood, sleep, and other brain functions. I am able to feel my seizures as they are come on. Sometimes, I experience an extremely bad headache and/or a strange feeling in my throat just before I have a seizure. When I force myself to go about my daily life while I am having functioning problems, or if I move around too fast, or even if I become frightened for any reason, I can have a seizure. Because I have a brain tumor my seizure specialist at Stanford Epilepsy Center tells me that my seizures could turn into epilepsy. My seizures are extremely painful. Sometimes, I have one seizure after another. They can trigger several of my other conditions and make all of my chronic pain conditions worse. When this happens I usually suffer for days having a combination of more seizures, and I will have body jerks, muscle spasms, and twitches, which cause excruciating pain that are unbearable for me to deal with.

41. Non-epileptic seizures can be caused by many different factors, including impaired blood flow to the brain, sleep disorders, severe chronic pain, psychological disturbances, and various other brain disturbances. It is not uncommon to see this type of seizure in individuals who have experienced a traumatic event or who are under various types of stress. In my case I have had a lifetime full of traumatic events, one after another. I have also had my share of severe chronic pain.

42. Cannabis helps slow down and minimize body jerks, muscle spasms, and twitches and helps to control the excruciating pain caused by my seizures. If I smoke or vaporize cannabis at the first onset of seizure symptoms, the cannabis can prevent the seizure. If I am unable to use cannabis in time to prevent the seizure, I need to medicate with cannabis when I am alert enough to smoke or vaporize to prevent another seizure.

43. *Inoperable Brain Tumor:* In 1999 an MRI showed I have a brain tumor. I have a circumscribed one centimeter densely enhancing tumor in the left petrous apex that mildly deforms the ventromedial aspect of the left temporal lobe. It is a Meningioma or a Schwannoma brain tumor. My doctors say the tumor is too deep for them to do surgery to remove it.

44. My doctor wants me to continue medicating with cannabis in the hope that, among its other benefits, it will prevent my brain tumor from growing.

45. *Uterine Fibroid Tumor:* In 2001 I was diagnosed with having a uterine fibroid tumor. Uterine Fibroids are benign tumors of muscle and connective tissue that develop within or are attached to the uterine wall. They slowly enlarge, frequently intruding into the cavity of the uterus or growing out beyond the normal boundary of the uterus. Even one small fibroid can cause many problems, sudden severe pain, and heavy menstrual bleeding. I have had several

problems with my tumor in this past year. I suffer from sensations of fullness and pressure in my lower abdomen, severe pelvic cramping, abdominal fullness, and an increase in urinary frequency. The biggest problem is extremely heavy menstrual bleeding. I bleed so fast that I suffer from light-headedness and become dizzy and nauseous to the point of almost passing out. I have always had nausea but it is now worse than before. The heavy bleeding and the severely painful menstrual periods tend to keep me down flat on my back for two or three days per month. Cannabis helps minimize monthly PMS symptoms. Cannabis helps relax my pelvic muscles, helps minimize pelvic pain, and helps release my muscle spasms and cramps, allowing me to function more easily physically.

46. *Recent Spinal Injury:* The effects of my scoliosis worsened several months ago after a very large man fell on my head, injuring my neck and back. The injury caused excruciating pain at the site of the injury, excruciating burning pain in my vertebrae, nerve problems going down both arms, and difficulties with my thumbs. The injury also caused some of my other pain conditions (TMJ, Rotator Cuff Syndrome, Headaches) to worsen. After a few months, the resulting pain caused me to experience multiple episodes of seizures and muscle spasms, which were also painful in their own right, further exacerbating my other chronic pain conditions and their related symptoms, and creating new and painful secondary injuries. Perhaps most critically, the injury caused my Fibromyalgia Syndrome worsen (see paragraph 38).

47. *My Medical Cannabis Use:* Before I became a medical cannabis patient I was against recreational marijuana use. In late 1997, my doctor felt cannabis would be an effective medication to treat my many complicated and complex medical conditions, and gave me my first recommendation to use medical cannabis. I eventually became a member of the Oakland Cannabis Buyers'

Cooperative (OCBC) in early 1998, before the federal government filed suit against it. The OCBC was trying to provide me with medical grade cannabis. I was one of 14 "medical necessity" patients that the Oakland Cannabis Buyers' Cooperative was fighting for in the United States Supreme Court in 2001. The federal government, however, prevented the OCBC from giving me safe access to the one medication (medical cannabis) that keeps me alive. At that point I was forced to obtain my medication on the street. I was robbed, ripped off, and taken advantage of by the people selling the marijuana to me or to a friend on the street. Black market marijuana *is not* medical grade cannabis. One really does not know what is in that marijuana. It may contain mold, fungus, pesticides, other drugs, rat droppings, or god knows what. One does not know how it was grown or processed. It is just not safe.

48. To be safer and to save money, I tried to grow my own cannabis about five years ago. Even though I am good at growing most house plants, I found that I could not grow my own cannabis. Indoor cannabis *does not* grow like a weed, as some people think. The cannabis plants needed special care, and they needed more than I was able to give physically. I kept having insect problems and I did not have enough room or ventilation in my house. I could not grow enough medicine for my medical needs. Thus, as a single mother, to buy cannabis, I had to make choices such as which bills to pay that month, and whether I would have enough food to eat after I fed my children.

49. I am now blessed to have two wonderful caregivers who grow all of my medicine and are willing to take a huge risk with their own liberty to help keep me alive. That is true compassion. I am sure we would all be facing mandatory sentences just because we are growing a plant that happens to keep me alive and allows me to be here for my children. I would not be alive if it were not for these two caregivers. My caregivers both work very hard to help me

fight my diseases. My caregivers grow my medicine specifically for me. They do not charge me, nor do we trade anything. They grow my medicine and give it to me free of charge. They both grow different strains of cannabis for me to treat my medical conditions. One strain of medical cannabis helps my chronic pain, one helps my seizures, one helps me eat and hold onto my weight, and another may helps control my nausea. All of these different strains of medical cannabis are very beneficial and essential to my survival. Not all strains of cannabis work for me. Because the different strains have different growth cycles, one caregiver *could not* grow all of the medical cannabis I require to keep my weight up and my pain levels down. Moreover, I can not risk having all of my medicine in one place because I can not afford to lose my whole garden if there is a pest problem or if it were raided by federal agents. The caregivers who grow my medicine are my co-plaintiffs, known as in this litigation as JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO.

50. In the cultivation of my medical cannabis, JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO, of Oakland, California, use only soil, water, and nutrients originating from within the borders of the State of California. JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO also use only growing equipment, supplies, and lumber manufactured within the borders of the State of California. JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO cultivate for me medical-grade cannabis free of mold, fungus, pesticide residue, and other contaminates in the particular strains that I have found to be most effective in treating my specific medical conditions.

51. Both of my caregivers not only grow my medical-grade cannabis but they also process the cannabis into hashish or keif. Additionally, I process the cannabis into cannabis oil for cooking, I make cannabis therapeutic

massage oil, I make cannabis therapeutic skin balm, and I make cannabis foods.

52. I provide the following information to my caregivers to try to keep them safe and protect my medicine in case law enforcement agents raid the garden areas:

A. Copies of my doctors' recommendations for the use of medical cannabis,
B. A copy of my Oakland Cannabis Buyers' Cooperative I.D. Card that states I am a "medical necessity" patient and confirms that my recommendation is valid,
C. Copies of some of my medical records, and
D. A signed caregiver statement that says my caregivers provide my medical cannabis to me.

In total, my caregivers grow over eight pounds per year of medical-grade cannabis for me.

53. *Amount of Cannabis I Use:* I use over two and one-half ounces of processed medical cannabis per week, or over eight pounds of cannabis per year. Cannabis does not get me "high." I cook and bake my own cannabis foods. I use my homemade cannabis oils to make massage oil and balm that I use to rub over my body, which helps my muscle spasms and cramps. I even used it on my stitches after surgery. It works like a miracle on rashes and hives. The worst side effect is the fear that at any moment the DEA could kick my door in and cause my and my family irreparable harm. My children, my husband, and myself are all aware of the risks we have been taking in order to keep me alive. We are willing to risk it all by telling about our family, and telling the Court all about my medical use of cannabis. Is the only effective way for me safely to treat all of my many medical conditions without becoming sicker. With cannabis I do not suffer from the side effects I experience with synthetic prescription medications. I am not

a medical cannabis patient because I choose to be one -- I am a medical cannabis patient because it is a necessity to keep me from dying. Taking a pill would be much easier and would take less time, but I simply do not have that option the way most others patient do. I have no other medical or legal alternative to sustain my life. Cannabis saved my life and gave my children their mother back. I would rather use cannabis to end the suffering from my conditions, and be alive, than to suffer endlessly knowing that there *is* something that could help treat my serious medical conditions. Cannabis is the only medication that keeps me alive and makes my medical conditions more manageable and my life livable.

54. *How I Use Medical Cannabis:* I smoke or vaporize cannabis every two waking hours, and have every day since late 1997. Upon starting to use cannabis in 1997 I immediately noticed a huge difference in my medical conditions. I noticed an even bigger difference in 1998 when I started to ingest medical cannabis by eating cannabis brownies, cakes, candy, and milk. Using the smoked and vaporized cannabis and the ingested cannabis at the same time made the biggest improvement in my medical conditions. One of my problems is I am unable to sleep due to high levels of pain. If I am lucky enough to fall asleep, I may wake up in the middle of the night in tears. When I eat cannabis before bedtime it helps me sleep better. Rest is important for my healing process. Cannabis massage oil and balm used topically on my muscles and joints makes a big difference. Using all of these methods together seems to make the biggest impact on my health, and helps me to manage and cope better on a daily basis. It has made all the difference in the world. My doctors noticed, my children noticed, my friends noticed.

55. It is a miracle I am now walking, it is a miracle I am even alive. I still have functioning problems and extremely high levels of pain even with the cannabis,

however cannabis controls the pain enough so I can walk again, and it keeps me from wasting away and starving to death. I am not willing to give up my life or go back into a wheelchair without a fight. Cannabis really does help my conditions. It keeps me alive and helps minimize my suffering. My cannabis use and doctors' recommendations are all documented in my medical records.

56. I know I am taking a huge risk by talking publicly about my medical cannabis use. I am in no way going to stop using cannabis. I am fighting to stay alive. I want to live! I am extremely afraid of being raided by federal agents. The fear I experience is having a negative effect on my medical conditions. If I am raided by federal agents or incarcerated and kept from using my medicine, I would be gravely ill in a short amount of time. My children need me to take care of them and help them grow up. I have never been arrested nor am I a threat to anyone. I am just a mother who is fighting to stay alive. I feel the United States Attorney General and the DEA Administrator Asa Hutchinson are waging a civil war against the sick, disabled, and dying Americans of our country. I am filing this lawsuit to fight for my constitutional right to life.

57. *My Media Attention:* Because of all the media coverage I have received, I am at greater risk of being raided by the federal government. After cannabis had freed me from my wheelchair I became more active in helping California medical cannabis patients. After the Supreme Court's 2001 decision in the Oakland Cannabis Buyers' Cooperative case, I received significant national and international media coverage. My photos and quotes were used in many newspapers across the United States, including the *New York Times* and *USA Today*. I spoke on national television saying I could not follow any federal law that purported to prevent me from using cannabis. Since then I have spoken at numerous events and conferences educating the public about the use of medical cannabis. I have taught

classes on medical cannabis at high schools and colleges, and police academies.

58. *My Community Education and Community Service Activities:* I do my best to become involved in my community when my body allows me to participate. I am on the Oakland City Council's Medical Cannabis Task Force. I work with the Alameda County Public Health Department and the Alameda County Department of Children and Family Services regarding medical cannabis issues. I have spoken before city councils. I do not want other patients to suffer as I have to. We need to be taken off the battlefield of the "Drug War" right away. My life depends upon it. I feel I have been left with no choice: I have no alternative but to speak out. However, I fear that makes me an easy target based on numerous raids by federal agents against patients and growers. Outspoken patients have recently been targeted and raided by federal agents.

59. *How My Medical Conditions and My Use of Medical Cannabis Affected My Children:* My children have had a very difficult time adjusting to my many complex medical conditions. They know more than anyone how medical cannabis brought their mommy back to them. Before 1995, I was the neighborhood mother, who played basketball, roller bladed, played frequently with the children, managed my son's little league baseball team, and helped at the school. We would have all of the neighborhood children over to bake cookies, and we would do children's hobbies and crafts. We did all kinds of wonderful and fun things together. Our lives have never been the same since I became disabled, and never will be normal again. My medical conditions have affected my children emotionally. When I became disabled in September 1995, my daughter had just started kindergarten. She was so little that she just did not adjust well to my medical conditions. At that young age my daughter would actually hit me when I was in my wheelchair. She was so angry because her mommy was gone, replaced by

my diseases. My daughter was trying to beat the disease out of my body. My daughter was too little to understand what was happening to her mommy. She would lay on her bed and cry with sadness. I was unable to hold my daughter in my arms as I used to because the burning pain in my body would become worse if someone touched my skin, and my body was very debilitated. I really missed holding both of my children. I love them so much, I would do anything for them and I would do anything to keep them safe from harm. As the years passed my body continued to deteriorate, and I became weaker and weaker. The weaker I became from my diseases, the harder it was for my children.

60. One night I hard my daughter crying in bed. I went to her side and asked her why she was crying. She told me she was crying because I was disabled and sick. She wanted me to get out of my wheelchair. She wanted her mommy back. She asked me why, why can't I get better, why does her mommy have to be in a wheelchair. She cried for a long time. She often cried at night about my medical conditions. She missed me. It broke my heart. I told her to keep praying and maybe God would answer her prayers. I thought prayer was the best thing. She told me she had been praying and God did not hear her prayer. I told her to keep praying and ask Him to answer her and maybe her prayers would come true.

61. I do my very best to be there to support both of my children. My children and I have a great open communication. They know they can talk to me about anything. I have to protect my children and do what is in their best interests.

62. Both of my children know that medical cannabis *is* legal under California State law. I asked my children if they wanted me to stop using my medicine because of the federal government. They both told me, "No Way." The expression on their little faces said it all. My children know

that I am alive today because of medical cannabis. I do not want the DEA to raid my home and traumatize me or my family.

63. Medical cannabis has only medical benefits for me, I have not had one single negative experience from using cannabis medically. The most scary side effect is knowing that at any moment federal agents could kick my door in and hold me and my family prisoner. My children and my husband are all aware of the risks they have been taking in order to keep me alive. We are now willing to risk even more by disclosing my medical use of medical cannabis under oath herein.

64. *Conclusion:* For years I felt as if I was suffering in Hell. What I had to endure was unbelievable and indescribable torture. Somehow, I found a miracle sent down from heaven by an angel that brought me up from the pits of Hell, and saved my life. I was given medical cannabis! My life was saved by this new miraculous medicine and my life was forever changed. Healing had begun, and healing was my gift. I have seen the changes in my body, my doctors have seen the changes in my body, and my family and friends have seen my miracle. I am sorry, I can not stop using medical cannabis or I will die. I am not giving up the miracle I have been given to save my very life. I will not go back to Hell for anyone or anything. I implore the federal government not to take my life from me. I want to live and grow in peace.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on this 25th day of October, 2002, in Oakland, California.

/s/ ANGEL McCLARY RAICH
ANGEL McCLARY RAICH

Supreme Court, U.S.
FILED
JUN 10 2004
OFFICE OF THE CLERK

No. 03-1454

In the Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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In the Supreme Court of the United States

No. 03-1454

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL., PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

The Ninth Circuit has held that Congress lacks the power under the Commerce Clause to proscribe the intrastate possession, manufacture, and free distribution of marijuana for purported medicinal use. That holding is unprecedented, conflicts with the decisions of numerous other courts of appeals, and partially invalidates the Controlled Substances Act (CSA), an Act of Congress that is central to combating illegal drug possession, manufacture, and distribution throughout the country. The decision clearly warrants this Court's review.

A. The Court of Appeals' Decision Significantly Undermines The Government's Enforcement of The CSA

1. The court of appeals' decision merits this Court's review because it partially invalidates an Act of Congress on constitutional grounds and "the decision raises significant questions as to the ability of the United States to enforce the Nation's drug laws." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489 (2001). The legal and practical impact on the Ninth Circuit's decision is extraordinary. Since the filing of the government's petition, not only has the significant litigation set forth in the petition continued

unabated (Pet. 22- 24), but the court of appeals' decision has spawned new impediments to the federal government's ability to enforce the CSA. For instance, on April 21, 2004, a district court held that, in light of *Raich*, a cooperative of 250 members was entitled to a preliminary injunction that bars the federal government from enforcing the CSA against the cooperative's marijuana manufacturing and distribution operations. *Country of Santa Cruz* v. *Ashcroft*, No. C 03-01802 JF, 2004 WL 868197 (N.D Cal.). The court reached that result despite the cooperative's distribution of marijuana to many persons and its collection of financial contributions from its members and others to support its operations. The court found its holding compelled by the Ninth Circuit's decision in this case "[a]bsent intervention by the Supreme Court." 2004 WL 868197, at *7.

Similarly, the Ninth Circuit recently relied on *Raich* to order the release from prison of an individual who is currently appealing two marijuana convictions arising out of his manufacture of more than 1500 marijuana plants for purported medicinal use. The Ninth Circuit found that bail pending the defendant's appeal was warranted because its decision in *Raich* "changed the legal landscape on the issue of the permissible reach of the Controlled Substances Act in circumstances where it is asserted that the drug involved is marijuana, the use is for medicinal purposes, and the use is strictly local." *United States* v. *Alden*, No. 02-10673 & 10674, at 2 (Mar. 30, 2004). Moreover, the magistrate judge who imposed the conditions of bail release also declined to order otherwise mandatory drug testing of the defendant, explaining that, after the decision below, courts must "tread very lightly" on marijuana activities for purported medical use. *Marijuana Convict Won't Face Drug Testing*, Tri-Valley Herald, Apr. 27, 2004, at 6.

In short, the Ninth Circuit's decision not only held the CSA unconstitutional as applied to individuals such as respondents who allege that they locally use, manufacture, and distribute marijuana, but the decision also has prevented

the government from applying the CSA to entities and individuals engaged in widespread marijuana manufacturing and distribution.[1]

The Ninth Circuit's partial invalidation of the CSA also threatens a substantial increase in the level of prohibited drug activity in States within the Ninth Circuit. Respondents rely on the fact that only a small percentage of the population in those States reportedly use marijuana for asserted medical purposes. Br. in Opp. 16-17. Those static figures, however, do not account for the dynamic effect of the decision below. Respondents' figures represent only individuals who admit they engaged in marijuana-related activity despite a blanket *federal* prohibition against any such activity (outside the narrow scope of use authorized by the CSA). The Ninth Circuit's decision has now removed that federal prohibition.

2. In opposing certiorari, respondents concede that the decision below "presents questions of great importance" but they argue that this Court's review should be deferred because the decision is interlocutory (Br. in Opp. 11) and because respondents would be entitled to a preliminary injunction on alternative grounds (*id.* at 12). Neither of those contentions justifies leaving the constitutional validity of the CSA in doubt pending further proceedings.

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[1] Respondents erroneously argue that John Does One and Two "cultivate" marijuana without engaging in "distribution" when they thereafter provide Raich with the drug. Pet. 7 n.7. The CSA defines the term "distribution" to include "the actual, constructive, or attempted transfer" of marijuana. 21 U.S.C. 802(8) and (11). The record shows that "John Does Number One and Two * * * are caregivers who *distribute* marijuana." Pet. App. 64a n.10 (emphasis added); accord *id.* at 5a ("These caregivers *provide* Raich with marijuana free of charge."); Br. in Opp. App. 37a (Declaration of Raich) ("they grow my medicine and "*give* it to me free of charge.") (emphasis added).

a. *A remand for further proceedings is unnecessary*

The petition presents the purely legal question whether Congress has the power under the Commerce Clause to regulate the wholly intrastate possession, manufacture, and distribution without charge of marijuana for asserted medical use. No further factual development or proceedings are needed for this Court to resolve that legal issue. Pet. 21, 24. Indeed, after the filing of the government's petition in this case, the district court on remand entered a preliminary injunction enjoining the Attorney General and the Administrator of DEA "from arresting or prosecuting Plaintiffs Angel McClary Raich and Dianne Monson, seizing their medical cannabis, forfeiting their property, or seeking civil or administrative sanctions against them with respect to the intrastate, noncommercial cultivation, possession, use, and obtaining without charge of cannabis for personal medicinal purposes on the advice of a physician and in accordance with state law, and which is not used for distribution, sale, or exchange." Preliminary Injunction Order, *Angel McClary Raich* v. *John Ashcroft*, No. C 02 4872 MJJ (N.D. Cal. May 14, 2004), at 1- 2.[2]

There also is no basis for deferring this Court's review pending further proceedings to determine whether the activities of individuals who are similarly-situated to respondents substantially affect commerce. Br. in Opp. 11-12. The relevant class of activities is the CSA's *comprehensive* regulation of the interstate possession, manufacture, and distribution of controlled substances generally, which indisputably takes place in interstate commerce and substantially affects interstate commerce. Pet. 10-20. Whether Congress constitutionally found it necessary and proper to regulate respon-

[2] Respondents suggest that proceedings on remand might shed light on whether the case is ripe or they have standing. That is not correct. Respondents have standing and the case is ripe because respondents are admittedly engaged in flagrant violations of the CSA, and the DEA already has taken enforcement action against respondent Monson by seizing her six marijuana plants.

dents' activities in order to effectuate its comprehensive and closed scheme of interstate drug regulation is purely a legal question that does not turn on a district court's findings of fact. *E.g.*, *Sabri* v. *United States*, 124 S. Ct. 1941, 1946-1947 (2004). As this Court recently explained, "Congress' Commerce Clause power 'may be exercised in individual cases without showing any specific effect upon interstate commerce' if in the aggregate the economic activity in question would represent 'a general practice . . . subject to federal control,'" and "[o]nly that general practice need bear on interstate commerce in a substantial way." *Citizens Bank* v. *Alafabco, Inc.*, 539 U.S. 52, 56-57 (2003) (per curiam) (quoting *Mandeville Island Farms, Inc.* v. *American Crystal Sugar Co.*, 334 U.S. 219, 236 (1948)).

Moreover, even if the relevant class of activities were confined to respondents' conduct, it would not matter. Congress has already made the factual determination that wholly intrastate drug use, production, and distribution in the aggregate substantially affects the interstate drug market. 21 U.S.C. 801; see Pet. 3-5, 12-15. Congress's findings apply with equal force to all schedule I drugs, including marijuana, and without regard to whether the purported use is medicinal or otherwise. Indeed, the CSA lists marijuana as a schedule I drug precisely because it has no currently accepted medical use, 21 U.S.C. 812(b)(1)(A)-(C), and the CSA accordingly bans all possession, manufacture, and distribution of marijuana outside the confines of the CSA even for an asserted medical necessity. *Oakland Cannabis*, 532 U.S. at 491, 494 n.7; Pet. 2-3, 16-18.[3]

[3] Respondents fault the government for describing their activities as involving the "purported" "medicinal" use of marijuana. Br. in Opp. 5 n.5. That description accurately reflects Congress's definitive judgment that marijuana has no recognized medical use. Moreover, the Institute of Medicine (IOM) report relied upon by respondents (*id.* at 3) is not a "study." Rather the IOM reviewed the existing scientific evidence concerning possible medical uses of marijuana and recommended that further research be devoted, not to developing marijuana as a licensed drug, but to developing a method of delivering cannabinoids without the serious

b. *Respondents' alternative contentions lack merit*

Respondents also contend that they would remain entitled to a preliminary injunction even if the Court reversed the Ninth Circuit. In particular, they argue that their activities are protected by the doctrine of medical necessity (Br. in Opp. 25- 27) and the Fifth and Tenth Amendments (*id.* at. 23, 27-30). The district court correctly rejected each of those contentions, however, Pet. App. 58a-65a, and the court of appeals did not review those aspects of the district court's decision. *Id.* at 9a. Moreover, respondents cite to no decision adopting any of their contentions. Accordingly, were the Court to grant certiorari and reverse the Ninth Circuit's Commerce Clause holding, the appropriate course would be to remand the matter to the Ninth Circuit for it to consider respondents' other contentions in the first instance. See, *e.g.*, *Oakland Cannabis*, 532 U.S. at 495 n.7 (declining to reach respondents' contention that the CSA as applied to them violated the Commerce Clause). Thus, a reversal by this Court would remove the basis for the district court's preliminary injunction.

Respondents' other arguments fare no better than their Commerce Clause argument. First, as noted by respondents (Br. in Opp. 27 n.19), this Court in *Oakland Cannabis* has already rejected the distinction between a claimed medical necessity to manufacture and distribute marijuana and a claimed medical necessity to posses it. 532 U.S. at 494 n.7. Moreover, this case involves the manufacture and distribution of marijuana, as well as possession. Second, if this Court

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adverse health consequences associated with smoking marijuana. See IOM, *Marijuana and Medicine: Assessing the Science Base* 10-11 (Janet E. Joy, Stanley J. Watson, Jr. & John A. Benson, Jr. eds., 1999) ("Because marijuana is a crude THC delivery system that also delivers harmful substances, smoked marijuana should generally not be recommended for medical use."). Similarly, although respondents point out that Marinol is a lawful drug that contains THC (Br. in Opp. 3 n.3), respondents do not (and could not) dispute that *marijuana* is a schedule 1 controlled drug that has never been approved for any medical use by the FDA. Pet. 17 n.4.

rejects respondents' Commerce Clause argument, that holding would doom respondents' Tenth Amendment argument. In cases that do not involve specific circumstances such as the federal commandeering of state governments or officials, the Tenth Amendment "states but a truism that all is retained which has not been surrendered," *United States* v. *Darby*, 312 U.S. 100, 124 (1941), and "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." *New York* v. *United States*, 505 U.S. 144, 156 (1992).

Finally, the CSA does not violate respondents' asserted fundamental right to use marijuana for purported medical purposes despite Congress's judgment that it is dangerous to public health and safety and has no currently accepted medical use. Pet. App. 61a-63a. There is no such fundamental right, and in any event, Congress has established procedures to remove marijuana from schedule I if the drug no longer satisfies the criteria for that schedule (21 U.S.C. 811), and has provided the Food and Drug Administration (FDA) with authority to approve marijuana should it be shown to have a medical use (21 U.S.C. 355). Congress also permits individuals to participate in research projects that have been registered with the DEA and approved by the FDA. 21 U.S.C. 355(i), 823(f). Significantly, respondents do not assert that they have invoked any of those statutory mechanisms.

B. The Ninth Circuit Erroneously Concluded That Congress Lacked The Power to Regulate The Manufacture, Possession, And Free Distribution of Marijuana

1. In defending the Ninth Circuit's decision on the merits, respondents attempt to distinguish *Wickard* v. *Filburn*, 317 U.S. 111 (1942), on the theories that *Wickard* involved a commercial farm that produced wheat; the statute at issue in *Wickard* exempted the production of small quantities of wheat; and the production of wheat in *Wickard* had a

more substantial effect on interstate commerce than the medicinal use of marijuana. Br. in Opp. 14-17. Those contentions fundamentally miss the import of *Wickard*'s aggregation principle. In *Wickard*, the Court held that Congress had authority under the Commerce Clause to regulate the production of home-grown wheat, even though the wheat was not "sold or intended to be sold," 317 U.S. at 119; the production "may not be regarded as commerce," *id.* at 125, and the regulated individual's own activity "may be trivial by itself," *id.* at 127. The Court reached that result because regulation of the local activity was necessary to achieve Congress's broader regulation of the interstate wheat market, an area indisputably within Congress's power. *Id.* at 127-129. As this Court later explained, *Wickard* stands for the proposition that Congress's regulation of wholly intrastate and non-commercial activity may be sustained as "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *United States* v. *Lopez*, 514 U.S. 549, 561 (1995).

Despite that principle, the court of appeals found the relevant class of activities to be narrowly confined to respondent's activities and then determined that Congress had not sufficiently found that the wholly intrastate use of marijuana for asserted medical purposes substantially affects commerce. Pet. App. 9a-23a. Respondents simply reiterate the same mistaken reasoning. Br. in Opp. 17-21. That reasoning ignores the comprehensive nature of the CSA and the need to regulate all drug activity to achieve the CSA's purpose of establishing a nationwide and closed system of drug distribution, as well as Congress's specific findings that intrastate drug activity *does* substantially affect interstate commerce.

2. For those reasons, respondents err in asserting that the Ninth Circuit's decision does not conflict with the decisions of other courts of appeals that have rejected Commerce Clause challenges to the CSA as applied to the local manufacture and simple possession of marijuana. Br. in Opp. 13. In contrast to the Ninth Circuit, the Second, Fourth, and Eighth Circuits have held that the relevant class of activity is the general class of activity regulated under the CSA *as a whole*. Pet. 18-20.

Respondents' attempt to isolate their asserted *medical* use of marijuana as the relevant class of regulated activity (Br. in Opp. 13) is misplaced. For purposes of Congress's power under the Commerce Clause, the asserted *use* of a drug—medical or otherwise—is irrelevant. Congress regulates marijuana as a *substance*, regardless of its asserted use, and respondents' judgment that Congress's purposes in passing the CSA apply with less force when the substance's use is asserted to have a medical utility is simply a policy disagreement with Congress's decision to address the problems posed by marijuana and other schedule I substances though a broad prohibition. Pet. 16-18.

Regardless of the motive for drug use, Congress was entitled to conclude that the intrastate regulation of marijuana—a drug that is regularly bought and sold in a defined, substantial, and well-established interstate and commercial market—is "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561. Congress reasonably determined that it was necessary and proper to guard against the significant risk that the local use, manufacture, and free distribution of marijuana would increase the interstate supply and marketing of marijuana; that local users would ultimately purchase marijuana in the black market to fill their asserted medical needs (for instance, should their production efforts fail or fall short) or, conversely, that local users would ultimately sell or divert the drug (for instance, should their production exceed their purported need); and that there would be difficult questions of proof in determining whether any given quantity of processed marijuana resulted from a commercial or interstate exchange. 21 U.S.C. 801; Pet. 11-14.

The absence of congressional authority to regulate the intrastate use, manufacture, and free distribution of marijuana would fundamentally undercut the congressional scheme. Individuals such as respondents who produce, consume, and distribute marijuana would be exempt from federal regulation. Although respondents counter that state law provides some regulation (Br. in Opp. 23-24), state law does not purport to establish anything like the comprehensive statutory and regulatory controls established by the CSA. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306; Pet. 15.

More fundamentally, respondents ignore Congress's judgment that the best way to regulate the manufacture and distribution of marijuana—a power Congress clearly possess and numerous cases have recognized—is to ban all use, manufacture, and distribution except within the narrow confines of the Act. The regime permitted by the Ninth Circuit's decision ignores that judgment and would let a *schedule I* controlled substance be consumed, manufactured, and distributed. Pet. 14-17. Because Congress rationally and permissibly determined that such activity was integrally related to the economic and interstate activity of drug trafficking, the Ninth Circuit's partial striking of an Act of Congress as unconstitutional warrants this Court's review.

* * * * *

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

THEODORE B. OLSON
Solicitor General

JUNE 2004

SUPREME COURT, U.S.
FILED
AUG 11 2004
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(5)

No. 03-1454

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v.
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ON WRIT OF CERTIORARI TO
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FOR THE NINTH CIRCUIT

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PETITION FOR A WRIT OF CERTIORARI FILED: APR. 20, 2004
CERTIORARI GRANTED: JUNE 28, 2004

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Docket No. 03-15481

ANGEL MCCLARY RAICH, DIANE MONSON, JOHN DOE (NUMBER ONE), JOHN DOE (NUMBER TWO),
PLAINTIFFS-APPELLEES

v.

JOHN ASHCROFT, ATTORNEY GENERAL, AS UNITED STATES ATTORNEY GENERAL, ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS-APPELLANTS

DOCKET ENTRIES

DATE	PROCEEDINGS
3/21/03	DOCKETED CAUSE AND ENTERED APPEARANCES OF COUNSEL. CADS SENT (Y/N): yes. Preliminary Injunction appeal, Moatt will set briefing schedule. [03-15481] (dg) [03-15481]
3/21/03	Filed Civil Appeals Docketing Statement served on (to CONFATT) [03-15481] [03-15481] (dg) [03-15481]
3/31/03	Filed order MOATT (JES) within 7 calendar days of the filing date of this order, the parties shall make arrangements parties to

DATE	PROCEEDINGS
	obtain from the ctr an official rt of proceedings in the DC which will be included in the roa. The brfing schedule is set as follows: the opening brf is due not later than 4/9/03; the answering brf is due 5/7/03, or 28 days after service of the opening brf, whichever is earlier; and the optional rpy brf is due within 14 days of service of the answering brf. If aplts fail to file an opening brf, this appeal will be dismissed automatically by the clk for failure to prosecute. This appeal and any motions pending when brfing is completed shall be referred to the next available motions panel for disposition. [03-15481] (jr) [03-15481]
3/31/03	Rec'd aplts ntc of designation of reporter's transcript. RTs already filed and paid for. [03-15481] (jr) [03-15481]
4/15/03	Filed order MOATT (JES) This is a preliminary injunction appeal. Aplt's mtn for an extension of time to file the opn brief is granted. The opn breif is due not later than 4/23/03; the ans brief is due 5/21/03 or 28 days after service of the opn brief, whichever is earlier; and the opt rpy brief is due within 14 days of service of the ans brief. This appeal and any mtns pending when briefing is completed shall be referred to the next available mtns panel for disposition. [03-15481] (kkw) [03-15481]

DATE	PROCEEDINGS
4/23/03	Filed original and 15 copies aplts' opening brf (Informal: no) of 62 pages and five excerpts of record in 1 volume; served on 4/23/03. [03-15481] (jr) [03-15481]
4/23/03	Filed aplts' request for oral argument [03-15481]; served on 4/23/03 to (MOATT). [4718373] [03-15481] (jr) [03-15481]
4/30/03	Rec'd State of California, County of Alameda & City of Oakland's brf as amicus in 15 copies only of 17 pages (originally filed in 02-16335, 02-16534 & 02-16715) to MOATT w/copy of ltr requesting permission to file. [03-15481] (jr) [03-15481]
4/30/03	Filed Marijuana Policy, Rick Doblin & Ethan Russo's motion for leave to file amicus curiae brf in support of aplts; served on 4/30/03 to (MOATT w/copy of brf). [4724483] [03-15481] (jr) [03-15481]
4/30/03	Rec'd Marijuana Policy, Rick Doblin & Ethan Russo's amicus curiae brf in 15 copies of 18 pages; served on 4/30/03 to (MOATT w/motion to file). [03-15481] (jr) [03-15481]
5/5/03	Filed original and 15 copies CA Medical Assoc. & CA Nurses Assoc.'s amicus curiae brf of 21 pages; served on 4/30/03. [03-15481] (jr) [03-15481]

DATE	PROCEEDINGS
5/6/03	Filed order MOATT (JES) aplts' request for oral argument and the request for leave to file an amicus brf are referred to the panel assigned to hear the merits of this appeal. The brfing schedule established previously remains in effect. [03-15481] (jr) [03-15481]
5/16/03	7-day oral extension of time by phone to file aples' brf per (JES/MOATT). [03-15481] Aples' brf due 5/28/03. (jr) [03-15481]
5/29/03	Filed original and 15 copies aples' 62 page brf; served on 5/28/03. [03-15481] (jr) [03-15481]
6/10/03	Rec'd errata to brf of aples; served 6/9/03. [03-15481] (jr) [03-15481]
6/11/03	Filed original and 15 copies aplts' rpy brf (Inforamal: no) of 32 pages; served on 6/11/03. [03-15481] (jr) [03-15481]
6/18/03	Rec'd County of Butte's ltr dated 6/17/03 joining in the legal arguments of aplts Raich, Monson and amici State of CA, Cty of Alamed and City of Oakland. [03-15481] (jr) [03-15481]
7/10/03	Filed Angel McClary Raich, Diane Monson, John Doe, John Doe additional citations, served on 7/7/03. RECORDS FOR MERITS PANEL [03-15481] (gar) [03-15481]

* * * * *

DATE	PROCEEDINGS
7/25/03	Filed order (Edward LEAVY & Michael D. HAWKINS) this appeal from the denial of a request for a preliminary injunction is referred to the next available merits panel for disposition. The appeal shall be placed on the calendar during the week of 10/6/03, in S.F.. [03-15481] (jr) [03-15481]

* * * * *

8/1/03	CALENDARED: San Francisco Oct 7 2003 9:00 a.m. Courtroom 3 [03-15481] (th) [03-15481]
8/12/03	Filed aplts' motion to hear this case before the panel which will hear case 02-16534, 02-16335, 02-16715 & 03-15062; [03-15481] served on 8/12/03 FAXED to (PANEL for this case and related cases). [4815286] [03-15481] (jr) [03-15481]

* * * * *

9/11/03	Filed order (Deputy Clerk: CAC) aplt's motion to assign related cases for oral argument on the same date and before the same panel but to be argued separately with appeal #s 02-16335, 02-16534, 02-16715 & 03-15062 set for oral argument on 9/17/03, is DENIED. [4815286-1] in 03-15481. The clk

DATE	PROCEEDINGS
	will serve copies of the order in case #s 02-163335, 02-16524, 02-16715 & 03-15062. [03-15481, 02-16335, 02-16534, 02-16715, 03-15062] (jr) [02-16335 02-16534, 02-16715 03-15062 03-15481]
9/11/03	Filed order (Deputy Clerk: rr) the motion for leave to file amicus curiae brf of Marijuana Policy Project; Rick Doblin, PH.D.; and Ethan Russo, M.D. is granted. [4724483-1] The amicus curiae brf shall be filed forthwith. [03-15481] (jr) [03-15481]
9/11/03	Filed original and 15 copies Marijuana Policy, Rick Doblin & Ethan Russo amicus brf of 18 pages; served on 4/30/03. [03-15481] (jr) [03-15481]
	* * * * *
10/7/03	ARGUED AND SUBMITTED TO Harry PREGERSON, C. A. Beam, Richard A. PAEZ [03-15481] (tu) [03-15481]
	* * * * *
12/16/03	FILED OPINION: REVERSED AND REMANDED. (Terminated on the Merits after Oral Hearing; Reversed; Written, Signed, Published. Harry PREGERSON, author; C. A. Beam, dissenting; Richard A. PAEZ) FILED AND ENTERED JUDGMENT. [03-15481] (jr) [03-15481]

DATE	PROCEEDINGS
	* * * * *
1/26/04	[4957169] Filed original and 50 copies aples' petition for panel rehearing and petition for rehearing en banc 17 pages; served on 1/23/04 to (PANEL & ALL ACTIVE JUDGES). [03-15481] (jr) [03-15481]
1/26/04	Rec'd ntc of appearance of Mark B. Stern and Alisa B. Klein as csl for aples. [03-15481] (jr) [03-15481]
2/25/04	Filed order (Harry PREGERSON, C.A. Beam, Richard A. PAEZ) the petition for rehearing and for rehearing en banc is DENIED. [4957169-1] [03-15481] (jr) [03-15481]
3/5/04	MANDATE ISSUED [03-15481] (jr) [03-15481]

UNITED STATES DISTRICT COURT FOR THE
CALIFORNIA NORTHERN DISTRICT

CIVIL DOCKET No. 3:02-CV-04872

ANGEL MCCLARY RAICH, PLAINTIFF

v.

JOHN ASHCROFT, AS UNITED STATES
ATTORNEY GENERAL

DOCKET ENTRIES

DATE	DOCKET NUMBER	PROCEEDINGS
10/09/2002	1	COMPLAINT (*Summons Issued*) against John Ashcroft, Asa Hutchinson (Filing fee $150 receipt number 4406599). Filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (tn,) (Entered: 10/15/2002)
10/09/2002		Summons Issued as to John Ashcroft ; Asa Hutchinson (tn,) (Entered: 10/15/2002)
10/09/2002	2	ADR SCHEDULING ORDER: Case Management Statement due by 2/12/2003. Initial Case Management Conference set for 1:30 p.m. on 2/19/2003. (tn) (Entered: 10/15/2002)

DATE	DOCKET NUMBER	PROCEEDINGS
10/30/2002	3	Consent to Proceed Before a U.S. Magistrate Judge by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (tn,) (Entered: 10/31/2002)
		* * * * *
10/30/2002		Received Order re [4]: [*Proposed*] *Order granting motion to exceed page limitation* by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (tn,) (Entered: 10/31/2002)
10/30/2002	5	MOTION for Preliminary Injunction filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. Motion Hearing set for 12/4/2002 02:30 PM. (tn,) (Entered: 10/31/2002)
10/30/2002		Received Document re [5]: *[28 Pages] Memorandum of Law in support of motion for preliminary injunction* by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (tn,) (Entered: 10/31/2002)

DATE	DOCKET NUMBER	PROCEEDINGS
10/30/2002	6	DECLARATION in Support re [5]: *Of Frank Henry Lucido, M.D. in support of motion for preliminary injunction* filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (Related document(s)[5]) (tn,) (Entered: 10/31/2002)
10/30/2002	7	DECLARATION in Support re [5]: *Of Diane Monson in support of motion for preliminary injunction* filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (Related document(s)[5]) (tn,) (Entered: 10/31/2002)
10/30/2002	8	DECLARATION in Support re [5]: *Of Dr. John Rose in support of motion for preliminary injunction* filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (Related document(s)[5]) (tn,) (Entered: 10/31/2002)

DATE	DOCKET NUMBER	PROCEEDINGS
10/30/2002	9	DECLARATION in Support re [5]: *Of Angel McClary Raich in support of preliminary injunction* filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (Related document(s) [5]) (tn,) (Entered: 10/31/2002)
10/30/2002		Received Order re [5]: *[Proposed] Order Granting Motion for Preliminary Injunction* by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (tn,) (Entered: 10/31/2002)
		* * * * *
11/08/2002	11	Declination to Proceed Before a U.S. Magistrate Judge by John Ashcroft, Asa Hutchinson & *Request for Reassignment to a United States District Judge.* (tn,) (Entered: 11/12/2002)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
11/12/2002		Received Order *Order Granting Application for Admission of Attorney Pro Hac Vice of Randy E. Barnett* by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (ci,) (Entered: 11/18/2002)
11/13/2002	13	ORDER REASSIGNING CASE. Case reassigned to Judge Martin J. Jenkins for all further proceedings. . Signed by The Executive Committee on 11/13/02. (rcs) (Entered: 11/15/2002)
		* * * * *
11/19/2002	18	Memorandum in Opposition re [5] filed by John Ashcroft, Asa Hutchinson. (vlh,) (Entered: 11/20/2002)
		* * * * *
11/26/2002	22	Request for Judicial Notice filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (slh,) (Entered: 11/27/2002)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
12/05/2002	25	Request for Judicial Notice filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (vlh,) (Entered: 12/06/2002)
12/09/2002	26	MOTION to Dismiss filed by John Ashcroft, Asa Hutchinson. Motion Hearing set for 1/14/2003 09:30 AM. (slh,) (Entered: 12/09/2002)
		* * * * *
12/17/2002	29	Minute Entry: Motion Hearing held on 12/17/2002 before Judge Jenkins; that plaintiff's Motion for Preliminary Injunction [5] is submitted; defendant to prepare Order. (Court Reporter - Sahar Demos.) (slh) (Entered: 12/18/2002)
12/18/2002	30	ORDER by Judge Martin J. Jenkins vacating the 1/14/03 hearing on defendant's Motion to Dismiss [26]. (slh) (Entered: 12/19/2002)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
		* * * * *
03/03/2003	35	JOINT CASE MANAGEMENT STATEMENT filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (slh,) (Entered: 03/04/2003)
		* * * * *
03/05/2003	38	ORDER by Judge Martin J. Jenkins DENYING plaintiffs' Motion for Preliminary Injunction [5]. (slh) (Entered: 03/07/2003)
		* * * * *
03/12/2003	40	NOTICE OF APPEAL re [38] by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (Filing fee $105; receipt number 3345249) (slh,) (Entered: 03/13/2003)
03/12/2003		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re appeal [40] (slh,) (Entered: 03/13/2003)

DATE	DOCKET NUMBER	PROCEEDINGS
03/17/2003	41	CLERK'S NOTICE vacating the 3/25/03 hearing re: Motion to Strike and and the 4/8/03 hearing re: defendant's Cross-Motion for Leave to file statement of recent decision. (slh) (Entered: 03/19/2003)
03/18/2003	42	Minute Entry: Case Management Conference held on 3/18/2003 before Judge Jenkins. Matter stayed pending decision re: Interlocutory Appeal. (Court Reporter - NOT reported.) (slh) (Entered: 03/25/2003)
		* * * * *
03/19/2003	44	ORDER by Judge Martin J. Jenkins that this action is STAYED, pending resolution of the interlocutory appeal; all hearings and conferences in this matter are vacated; (Entered: 03/25/2003)
03/19/2003	45	ORDER by Judge Martin J. Jenkins that the part of footnote nine of the Court's 3/5/03 Order [38] shall be amended to read

DATE	DOCKET NUMBER	PROCEEDINGS
		"Judge Kozinski, in his concurring opinion in Conant v. Walters, 309 F.3d 629 (9th Cir. 2002)." (slh) (Entered: 03/25/2003)
03/26/2003		USCA Case Number re appeal [40]. USCA Case #03-15481 (slh,) (Entered: 04/01/2003)
03/28/2003	46	TRANSCRIPT DESIGNATION and Ordering Form for dates 12/17/02 (C/R: Sahar McVickar) by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (slh,) (Entered: 04/02/2003)
		* * * * *
04/16/2003	48	TRANSCRIPT for dates 12/17/02 (C/R: Sahar McVickar). (slh,) (Entered: 04/17/2003)
03/08/2004	49	USCA JUDGMENT reversing and remanding the decision of the District Court (re: Appeal [40]). (slh, COURT STAFF) (Filed on 3/8/2004) (Entered: 03/09/2004)
03/08/2004	50	CLERKS Letter Spreading Mandate to Counsel. (slh, COURT STAFF) (Filed on 3/8/2004) (Entered: 03/09/2004)

DATE	DOCKET NUMBER	PROCEEDINGS
03/11/2004	51	CLERK'S NOTICE: Status Conference set for 4/6/2004 02:00 PM. (slh, COURT STAFF) (Filed on 3/11/2004) (Entered: 03/12/2004)
		* * * * *
04/06/2004	53	Minute Entry: Status Conference held 4/6/2004 before Judge Jenkins; parties shall submit a form of order(s) re: preliminary injunction by 4/30/04. (Court Reporter - NOT reported.) (slh, COURT STAFF) (Date Filed: 4/6/2004) (Entered: 04/08/2004)
04/14/2004	55	Letter dated 4/14/01 from Robert A. Raich re: proposed preliminary injunctions. (slh, COURT STAFF) (Filed on 4/14/2004) (Entered: 04/16/2004)
04/15/2004	54	Letter Brief filed by Karen P. Tandy, John Ashcroft. (Attachments: # 1 Proposed form of Injunction) (Quinlivan, Mark) (Filed on 4/15/2004) (Entered: 04/15/2004)

DATE	DOCKET NUMBER	PROCEEDINGS
04/20/2004	56	Minute Entry: Telephone Status Conference held 4/20/04 before Judge Jenkins; parties shall submit draft alternate descriptive proposals regarding the John Does. (Court Reporter - NOT reported.) (slh, COURT STAFF) (Date Filed: 4/20/2004) (Entered: 04/21/2004)
04/23/2004	57	Letter Brief re [56] form of preliminary injunction order filed by John Ashcroft, Karen P. Tandy. (Related document(s) [56]) (Quinlivan, Mark) (Filed on 4/23/2004) (Entered: 04/23/2004)
		* * * * *
05/04/2004	59	Minute Entry: Telephone Status Conference held before Judge Jenkins; Telephone Status Conference set for 5/7/2004 03:00 PM if necessary.(Court Reporter - NOT reported.) (slh, COURT STAFF) (Date Filed: 5/4/2004) (Entered: 05/12/2004)

DATE	DOCKET NUMBER	PROCEEDINGS
05/14/2004	60	Letter Brief re [59] Proposed form of Preliminary Injunction Order filed by John Ashcroft, Karen P. Tandy. (Attachments: # 1 Proposed Order Proposed form of Preliminary Injunction Order # 2Exhibit Exhibit A) (Related document(s) [59]) (Quinlivan, Mark) (Filed on 5/14/2004) (Entered: 05/14/2004)
05/14/2004	61	PRELIMINARY INJUNCTION ORDER. Signed by Judge Martin J. Jenkins on 5/14/2004. (mat, COURT STAFF) (Filed on 5/14/2004) (Entered: 05/14/2004)
05/14/2004	62	Minute Entry: Telephone Status Conference held 5/14/04 before Judge Jenkins; letter brief and proposed Form of Preliminary Injunction Order e-filed today for Court's review and approval. (Court Reporter - NOT reported.) (slh, COURT STAFF) (Date Filed: 5/14/2004) (Entered: 05/18/2004)
06/02/2004	63	Declaration of Robert Raich pursuant to Preliminary Injunction Order 61 (filed UNDER

DATE	DOCKET NUMBER	PROCEEDINGS
		SEAL) filed by John Doe Number One, John Doe Number Two, Diane Monson, Angel McClary Raich. (Related document(s) 61) (slh, COURT STAFF) (Filed on 6/2/2004) (Entered: 06/04/2004)
06/23/2004	64	NOTICE OF INTERLOCUTORY APPEAL as to 61 Preliminary Injunction by John Ashcroft, Karen P. Tandy. Filing fee $ exempt. Appeal Record due by 7/23/2004. (Quinlivan, Mark) (Filed on 6/23/2004) Modified on 6/24/2004 (slh, COURT STAFF). (Entered: 06/23/2004)
06/24/2004		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re 64 Notice of Interlocutory Appeal. (slh, COURT STAFF) (Filed on 6/24/2004) (Entered: 06/24/2004)
06/24/2004		Copy of Notice of Appeal and Docket sheet mailed to all counsel. (slh, COURT STAFF) (Filed on 6/24/2004) (Entered: 06/24/2004)
06/24/2004		Certificate of Record Mailed to USCA re appeal 64. (slh, COURT STAFF) (Filed on 6/24/2004) (Entered: 06/24/2004)

DATE	DOCKET NUMBER	PROCEEDINGS
06/30/2004	65	USCA Case Number 04-16296: RECEIPT OF ACKNOWLEDGMENT from the 9th Circuit Court of Appeals for 64 Notice of Interlocutory Appeal filed by John Ashcroft, Karen P. Tandy. (aaa, Court Staff) (Filed on 6/30/2004) (Entered: 07/06/2004)

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. 02-4872 EMC

ANGEL MCCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, AND JOHN DOE NUMBER TWO, PLAINTIFFS

v.

JOHN ASHCROFT, AS UNITED STATES ATTORNEY GENERAL, AND ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS

[Filed: Oct. 9, 2002]

COMPLAINT FOR DECLARATORY RELIEF AND FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

Plaintiffs ANGEL McCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, and JOHN DOE NUMBER TWO bring this action for declaratory, injunctive, and other relief, and on information and belief, hereby allege:

INTRODUCTION

1. The Defendants are unconstitutionally exceeding their authority by embarking on a campaign of seizing or forfeiting privately-grown wholly intrastate medical

cannabis from California patients and caregivers, arresting or prosecuting such patients and caregivers, mounting paramilitary raids against such patients and caregivers, harassing such patients and caregivers, and taking other civil or administrative actions against them. The Defendants purport to have authority for those actions under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

2. On November 5, 1996, the sovereign State of California and the People of the State of California, exercising their reserved powers and expressly retaining certain rights, duly enacted through the initiative process the Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5. The purposes of the Compassionate Use Act are "[t]o ensure that seriously ill Californians have the *right* to obtain and use marijuana for medical purposes" and "[t]o ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes . . . are not subject to criminal prosecution or sanction." Cal. Health & Safety Code § 11362.5(b)(1)(A), (B). (Emphasis added.) All of Plaintiffs' conduct is lawful under the Compassionate Use Act.

3. Defendants' actions are effectively preventing implementation of the Compassionate Use Act, thereby abrogating the powers and rights constitutionally reserved and retained by the sovereign State of California and the People of California under the Ninth and Tenth Amendments to the U.S. Constitution. Moreover, Defendants' actions are infringing on Plaintiffs' rights guaranteed by the Due Process Clause of the Fifth Amendment to the U.S. Constitution. Additionally, to the extent that Defendants purport to take their actions pursuant to an act of Congress, then such act

exceeds the powers of Congress granted under the Commerce Clause of the U.S. Constitution. Furthermore, the doctrine of Medical Necessity precludes Defendants' actions against Plaintiffs.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 2201.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 (e) and 1402(a)(1).

PARTIES

Plaintiffs

6. Plaintiff ANGEL MCCLARY RAICH ("ANGEL") is a seriously ill patient who would likely be dead today were it not for her use of medical cannabis. ANGEL suffers from numerous severe debilitating medical conditions for which cannabis uniquely provides relief. ANGEL's primary care physician, and all of her numerous specialist physicians, support ANGEL's use of medical cannabis. ANGEL is a Medical Necessity patient-member of the Oakland Cannabis Buyers' Cooperative, from which she used to obtain her medicine. Because ANGEL cannot cultivate her own cannabis, she now relies on two caregivers who provide cannabis to her without charge. ANGEL resides in Oakland, California.

7. Plaintiff DIANE MONSON of Butte County, California is a patient who uses medical cannabis on her doctor's recommendation to treat Severe Chronic Back Pain and Spasms. On August 15, 2002, following a three-hour standoff in MONSON's front yard, federal agents raided her home and seized her six (6) medical cannabis plants, in defiance of an urgent telephone plea

by Butte County District Attorney Mike Ramsey to U.S. Attorney John K. Vincent imploring him to spare MONSON's medicine.

8. Plaintiff JOHN DOE NUMBER ONE, of Oakland, California, cultivates cannabis on ANGEL's behalf, which he supplies to ANGEL free of charge, without any cost or remuneration whatsoever. In order to protect ANGEL's supply of medical cannabis, JOHN DOE NUMBER ONE sues in an anonymous capacity. In the cultivation of ANGEL's medical cannabis, JOHN DOE NUMBER ONE uses only water and nutrients originating from within the borders of the State of California. Further, JOHN DOE NUMBER ONE uses exclusively growing equipment, supplies, and materials manufactured within the borders of the State of California. JOHN DOE NUMBER ONE cultivates for ANGEL medical-grade cannabis free of mold, fungus, pesticide residue, and other contaminates in the particular strains and potencies that ANGEL has found to be most effective in treating her specific medical conditions.

9. Plaintiff JOHN DOE NUMBER TWO, of Oakland, California, cultivates cannabis on ANGEL's behalf, which he supplies to ANGEL free of charge, without any cost or remuneration whatsoever. In order to protect ANGEL's supply of medical cannabis, JOHN DOE NUMBER TWO sues in an anonymous capacity. In the cultivation of ANGEL's medical cannabis, JOHN DOE NUMBER TWO uses only water and nutrients originating from within the borders of the State of California. Further, JOHN DOE NUMBER TWO uses exclusively growing equipment, supplies, and materials manufactured within the borders of the State of California. JOHN DOE NUMBER TWO cultivates for ANGEL medical-grade cannabis free of mold, fungus, pesticide

residue, and other contaminates in the particular strains and potencies that ANGEL has found to be most effective in treating her specific medical conditions.

Defendants

10. Defendant JOHN ASHCROFT is sued in his official capacity as the Attorney General of the United States of America, which is one of the sovereigns in our federal system of Dual Sovereignty.

11. Defendant ASA HUTCHINSON is sued in his official capacity as the Administrator of the Drug Enforcement Administration (DEA), an agency of the United States of America, which is one of the sovereigns in our federal system of Dual Sovereignty.

MEDICAL BACKGROUND

12. As a mother of two children, Plaintiff ANGEL opposed all illegal drug use, including the recreational use of marijuana, until the benefits of cannabis became unmistakable for the treatment of ANGEL's own medical conditions.

13. ANGEL suffers from the following, often interrelated, medical conditions: a) Life-Threatening Weight Loss, Malnutrition, Cachexia, and Starvation; b) Chronic Nausea; c) numerous Severe Chronic Pain afflictions from: Scoliosis, Temporomandibular Joint Dysfunction Syndrome (TMJ), Endometriosis, Headaches, Rotator Cuff Syndrome, and Uterine Fibroid Tumor; d) Post Traumatic Stress Disorder (P.T.S.D.); e) Non-Epileptic Seizures; f) Fibromyalgia; and g) an inoperable Brain Tumor. Moreover, ANGEL endured four years of Paralysis, which confined her to a Wheelchair; her doctors said she would never walk again, but she then discovered cannabis as the only treatment that brought her Paralysis into complete remission.

14. ANGEL's doctors now recommend that she medicate with cannabis every two hours. She medicates by ingesting, smoking, and vaporizing cannabis. Her physicians emphatically insist that ANGEL "cannot be without this medicine" because severe Weight Loss and flare-ups of her Chronic Pain conditions would quickly develop. When ANGEL's Pain levels are elevated she is prone to having Seizures.

15. The Appendix hereto, *supra*, is a description of ANGEL's numerous complex medical conditions, and an explanation of how medical cannabis is the only effective treatment for her medical conditions. Plaintiffs reallege and incorporate by reference all paragraphs of the Appendix hereto as if set forth fully in the body herein.

16. Without access to medical cannabis, ANGEL would experience horrible pain, suffering, and death. Horrible pain suffering, and death constitute irreparable harm.

17. ANGEL requires over two and one-half ounces of cannabis per week, or in excess of eight pounds of cannabis per year, for her personal medical consumption. Angel is a member of the Oakland Cannabis Buyers' Cooperative (OCBC), and used to obtain her medicine there, but cannot now obtain her medicine from OCBC because of Defendant UNITED STATES OF AMERICA's actions against the OCBC starting in 1998. ANGEL lives in fear that her home will be raided, her medical cannabis will be seized, she or her caregivers will be arrested, or her property will be forfeited by Defendants' actions, whether or not the Defendants ever file criminal charges against her. Stress from that fear is further exacerbating ANGEL's already precarious medical conditions.

18. If Defendants were to take ANGEL into custody and deny her access to medical cannabis, she would suffer serious medical consequences within a matter of hours. Because of ANGEL's already fragile medical condition, even a raid by Defendants on ANGEL would trigger severe medical repercussions.

19. ANGEL is at particular risk of being targeted by the Defendants: ANGEL has been quoted in electronic and print media locally, nationally, and internationally as a medical cannabis patient, and has defiantly stated that, faced with the alternative of an agonizing death, she would continue to use medical cannabis notwithstanding the federal war on cannabis patients. Contrary to claims by Defendant HUTCHINSON, the Defendants are engaging in a campaign of selective prosecution targeting medical cannabis patients, especially the ones who have been most outspoken publicly.

20. ANGEL is a Medical Necessity Patient. She is one (1) of only fourteen (14) members designated as being a Medical Necessity Patient by the OCBC following rigorous and meticulous evaluations by the OCBC's medical and administrative staff. As discussed more thoroughly herein, ANGEL suffers from numerous serious medical conditions. She would suffer imminent harm if she did not have access to cannabis. She needs cannabis to treat her medical conditions or their symptoms. She has no reasonable alternative to cannabis because she is violently allergic to virtually all pharmaceutical medications.

21. Plaintiff DIANE MONSON has suffered from Severe Chronic Back Pain and Spasms since 1989. She first tried medical cannabis in 1998, and uses it on the recommendation of her doctors in light of its remarkable efficacy at controlling her symptoms. MONSON's

Spasms are an extremely painful experience in their own right, comparable in intensity to an uncontrollable cramp. Medical cannabis completely eliminates her Spasms. Even with medical cannabis, MONSON still experiences discomfort, but cannabis greatly relieves her Chronic Pain. Without cannabis, her spasms would return and she would be subjected to intense pain that cannot be relieved any other way. MONSON has tried various combinations of prescription pharmaceutical medications, but they are often ineffective and they always disrupt her quality of life by interfering with her ability to function. In contrast, MONSON has found cannabis to be both effective and free of undesirable side-effects.

LEGAL BACKGROUND

The Commerce Clause

22. Wholly intrastate activity is beyond the power of Congress "to regulate Commerce . . . among the several States," U.S. Const. Art. 1, sec. 8. *See The Federalist* 42 (J. Madison) (referring to the power "to regulate between State and State"). Protecting wholly intrastate commerce from the reach of Congress is a constitutional imperative in our federal system. To the extent the Controlled Substances Act purports to grant Defendants' authority to conduct the activities complained of herein, such Act exceeds the authority granted to Congress under the Commerce Clause. Plaintiffs seek protection for conduct that has no effect whatsoever on interstate commerce; indeed, Plaintiffs' conduct is not commerce at all.

State Sovereignty as Confirmed in the Tenth Amendment

23. The Tenth Amendment confirms that the power of the Federal Government is subject to limits that may, in a given instance, reserve power to the States. Although the Constitution delegates to Congress the power over interstate commerce and other national concerns, the States are primarily responsible for the health and safety of their citizens, a power known as the "police power." Traditionally, no power is more central to the sovereignty of the States, and Congress lacks such a power. State governments have authority to enact measures reasonably necessary to protect public health. Congress cannot exercise its power over interstate commerce to interfere with a State's police power by prohibiting *wholly intrastate* conduct that the State mandates in the interest of health or safety. Respect for the sovereign States that comprise our Federal Union imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to "serve as a laboratory" in the trial of "novel social and economic experiments without risk to the rest of the country." The only doctrine preventing federal usurpation of traditionally State regulated activities is that such federal actions would violate the principles of federalism. To the extent the Controlled Substances Act purports to grant authority for Defendants to prohibit the conduct for which Plaintiffs herein seek protection, the Act exceeds Congress's constitutional authority by abrogating powers reserved to the State of California.

Fundamental Constitutional Rights Protected by The Fifth and Ninth Amendments

24. The Due Process Clause of the Fifth Amendment provides protection of unenumerated liberties against the federal government. The Ninth Amendment also provides protection under its express injunction that: "The enumeration in the Constitution of certain rights shall not be construed to deny or disparage others retained by the people." U.S. Const. Amend. IX. To receive constitutional protection, an unenumerated liberty must have roots in "our Nation's history, legal traditions, and practices." Infringements upon fundamental liberties call for heightened scrutiny of the means by which Congress exercises its enumerated powers.

25. The rights to bodily integrity, to ameliorate pain, and to prolong life are closely related. They are distinct rights or specific aspects of the famous trinity of "life, liberty, and the pursuit of happiness" in the Declaration of Independence. These rights, with deep roots in our Nation's history, legal tradition and practice, permit decisions about one's body to be made free from governmental intervention. In the absence of a compelling interest that would be furthered by such a proscription, the government cannot, consistent with the Constitution, abridge these rights of Plaintiffs, who are seriously ill patients. No such compelling governmental interest exists.

26. The right to consult with one's doctor about one's medical condition is also a fundamental right deeply rooted in our history, legal traditions, and practices. Moreover, imperatives established by the sanctity of the physician-patient relationship prevent Defen-

dants' interference with Plaintiffs' ability to act on their doctors' treatment recommendations.

27. Plaintiffs herein are entitled to heightened protection against Defendants' interference with Plaintiffs' exercise of their fundamental rights and liberty interests. The Constitution does not allow Congress to authorize Defendants to deny or disparage the activities for which Plaintiffs seek protection herein.

The Medical Necessity Doctrine

28. The law in the Ninth Circuit specifically and expressly applies the medical necessity doctrine to those suffering patients who require medical cannabis. There is a class of people with serious medical conditions; for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; who will suffer serious harm if they are denied cannabis; and for whom there is no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects. Although the Supreme Court has determined the doctrine is not available to a medical cannabis *distribution cooperative*, the applicability of the doctrine for seriously ill *patients* was not before the Court, and was notably preserved by the Court's concurrence in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001).

29. Plaintiffs ANGEL and MONSON are seriously ill patients for whom there is no alternative means of avoiding starvation or extraordinary suffering without the benefits of medical cannabis. The medical necessity doctrine is available to these seriously ill patients to use

and obtain medical cannabis for their own personal medical treatment.

Credible Threat of Actual Harm

30. Plaintiffs' fears of being victimized by Defendants are not merely theoretical. Defendants are continuing, indeed in the past year have escalated, their attacks on medical cannabis patients protected by State law in California and other States. Since September 11, 2001, Defendants have terrorized more than 35 Californians because of medical cannabis, including many individual patients for merely their own personal cannabis medication—involving amounts as small as one (1) cannabis plant or one (1) ounce of medicine. During that same period, nearly half of all the federal marijuana cases filed in the Northern District of California have involved medical cannabis. In a public speech on February 12, 2002, Defendant HUTCHINSON asserted that enforcement of federal laws against medical cannabis was a "responsibility" of his agency. HUTCHINSON reiterated that sentiment in a September 30, 2002, letter to California Attorney General Bill Lockyer, claiming the DEA is "legally mandated" to enforce such laws. With particular reference to Plaintiff MONSON's six medical cannabis plants, HUTCHINSON praised their seizure, claiming such action was Defendants' "duty under Federal law". Defendants' tactics commonly involve commando-style raids against sick patients in their homes, the pointing of high-powered automatic weapons at patients, and traumatizing patients and their loved ones. The Defendants frequently target those patients who are the most outspoken critics of federal policy. Being victimized by Defendants once provides no security for patients: The Defendants have raided several patients on more than

one occasion—always seizing medical cannabis, and sometimes initiating prosecutions or forfeiture actions against patients' property. Defendants' threats to medical cannabis patients are not confined to California, but extend as well to patients in various other States that permit medical cannabis. Plaintiffs reasonably fear further victimization by Defendants if the Court does not grant the relief sought herein.

FIRST CAUSE OF ACTION

31. Plaintiffs reallege and incorporate by reference Paragraphs I through 30 as if set forth fully herein.

32. The Commerce Clause, Article 1, Section 8, of the U.S. Constitution provides that "Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes . . . ."

33. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any Plaintiff herein for intrastate noncommercial activities involving the personal medical cannabis of Plaintiffs ANGEL or MONSON would violate the Commerce Clause as applied to Plaintiffs.

SECOND CAUSE OF ACTION

34. Plaintiffs realize and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

35. The Fifth Amendment to the U.S. Constitution provides that "No person shall be . . . deprived of life, liberty, or property, without due process of law . . . ."

36. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any

Plaintiff herein for activities involving the personal medical cannabis of Plaintiffs ANGEL or MONSON would violate the Fifth Amendment as applied to Plaintiffs.

THIRD CAUSE OF ACTION

37. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

38. The Ninth Amendment to the U.S. Constitution provides that "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."

39. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any Plaintiff herein for activities involving the personal medical cannabis of Plaintiffs ANGEL or MONSON would violate the Ninth Amendment as applied to Plaintiffs.

FOURTH CAUSE OF ACTION

40. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

41. The Tenth Amendment to the U.S. Constitution provides that "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

42. Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against any Plaintiff herein for activities within the State of California involving the personal medical cannabis of Plaintiffs

ANGEL or MONSON would violate the Tenth Amendment as applied to Plaintiffs.

FIFTH CAUSE OF ACTION

43. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 30 as if set forth fully herein.

44. Under the doctrine of medical necessity, individual patients who (1) suffer from a serious medical condition, (2) will suffer imminent harm without access to cannabis, (3) need cannabis for the treatment of their medical condition or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of their medical condition or symptoms associated with the medical condition because they have tried all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects, may use and obtain medical cannabis for their own personal medical treatment.

45. Plaintiff ANGEL suffers from numerous serious medical conditions, would suffer imminent harm without access to cannabis, needs cannabis for the treatment of her medical conditions and to alleviate symptoms associated with the medical conditions, and has tried all other reasonable legal alternatives to cannabis and found them to be ineffective or to result in intolerable side effects.

46. Plaintiff MONSON suffers from a serious medical condition, would suffer imminent harm without access to cannabis, needs cannabis for the treatment of her medical condition and to alleviate symptoms associated with the medical condition, and has tried all other reasonable legal alternatives to cannabis and found

them to be ineffective or to result in intolerable side effects.

47. The doctrine of medical necessity permits Plaintiffs ANGEL and MONSON to use and obtain cannabis for their personal medical treatment free from the threat of Defendants' actions to raid, arrest, prosecute, punish, seize medical cannabis of, forfeit property of, or seek civil or administrative sanctions against them.

IRREPARABLE HARM

48. Plaintiffs have suffered and will continue to suffer irreparable harm due to Defendant's challenged actions and practices described in this Complaint.

49. Plaintiffs face, or treat, serious or life-threatening medical conditions requiring therapy with cannabis to alleviate increased suffering, illness, or death. Defendants' interference with Plaintiff patients' treatment, and the resulting increased risk of suffering, illness, and death, constitute irreparable harm.

50. Plaintiff patients have constitutional rights to obtain treatment to alleviate their suffering. Defendants' actions are creating well-founded fear by Plaintiffs that Defendants will attack Plaintiffs' persons, medicine, health, or property, thus exacerbating Plaintiff patients' already serious medical conditions and constituting irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court enter judgment as follows:

A. Issue a Preliminary Injunction during the pendency of this action and a Permanent Injunction enjoining Defendants from arresting or prosecuting

Plaintiffs, seizing their medical cannabis, forfeiting their property, or seeking civil or administrative sanctions against them for their activities with respect to any of the following:

(1) The possession of medical cannabis by Plaintiffs Angel McClary Raich and Diane Monson for their personal medical use;

(2) The ability of Plaintiff Angel McClary Raich to obtain medical cannabis from her Plaintiff caregivers, John Doe Number One and John Doe Number Two, for her personal medical use;

(3) The ability of Plaintiffs John Doe Number One and John Doe Number Two to cultivate and provide medical cannabis to Plaintiff Angel McClary Raich for her personal medical use;

(4) The processing of medical cannabis by Plaintiff Angel McClary Raich for her personal medical use; and

(5) The cultivation of medical cannabis by Plaintiff Diane Monson for her personal medical use.

B. Declare that enforcement of the Controlled Substances Act is unconstitutional to the extent it purports to prevent Plaintiffs from possessing, obtaining, manufacturing, or providing cannabis for Plaintiff patients' personal medical use.

C. Declare that the doctrine of Medical Necessity precludes enforcement of the Controlled Substances Act to the extent it purports to prevent ANGEL from possessing, obtaining, or manufacturing cannabis for her personal medical use.

D. Declare that the doctrine of Medical Necessity precludes enforcement of the Controlled Substances

Act to the extent it purports to prevent MONSON from possessing, obtaining, or manufacturing cannabis for her personal medical use.

E. Award Plaintiffs their reasonable attorneys' fees and costs.

F. Grant Plaintiffs such other and further relief as the Court deems just and proper.

Dated: October 9, 2002

Respectfully submitted,

ROBERT A. RAICH
DAVID M. MICHAEL
RANDY E. BARNETT

By: /s/ ROBERT A. RAICH
ROBERT A. RAICH
Attorneys for Plaintiffs

APPENDIX

MEDICAL CONDITIONS OF PLAINTIFF ANGEL McCLARY RAICH

51. Plaintiffs incorporate by reference all paragraphs in this Appendix as if set forth fully in the body of this document.

52. *Life-Threatening Weight Loss, Malnutrition, Cachexia, and Starvation:* ANGEL experiences great difficulty maintaining a healthy weight. ANGEL's physicians, including her gastroenterologist, are unable to diagnose the root cause of her weight problems or to prescribe an effective course of treatment. One fact, however, is clear: ANGEL literally cannot eat without a sufficiently high level of cannabis in her system. Without cnnabis, ANGEL's weight can drop precipitously and she runs the very real risk of Malnutrition and Starvation. One result of Starvation is death. Death constitutes irreparable harm.

53. *Nausea:* ANGEL experiences chronic Nausea, which makes eating and drinking difficult, and exacerbates her wasting weight loss conditions. Even the smell, sight, or taste of food can trigger the nausea, and eating can cause stomach cramps leaving ANGEL in wrenching pain. Pharmaceutical anti-nausea medications are ineffective, but cannabis is the only medicine that provides relief.

54. *Severe Chronic Pain:* Every second that she is awake, ANGEL experiences Pain from one or more of the Chronic Pain conditions from which she suffers. She suffers greatly from Pain every single day. Sleep provides meager escape from the everpresent [*sic*] Pain she experiences. Her pervasive Pain and other conditions have made ANGEL permanently disabled. The prolonged Pain and suffering from her medical conditions significantly interferes with the quality of her life. Because ANGEL has an extremely high pain threshold, she is occasionally able to function when going about her life. On frequent occasions, however, the Pain becomes so great that ANGEL experiences difficulty performing everyday activities, or the Pain is so overpowering that she becomes completely debilitated and cannot get out of bed. When her nervous system becomes too overloaded with Pain, ANGEL experiences Muscle Spasms and Seizures. ANGEL's treatment is complicated by the fact that she is violently allergic to almost all pharmaceutical medicines. Cannabis, however, has the effect of making it easier for ANGEL to tolerate her constant Pain, although it does not make the Pain go away. Without cannabis, ANGEL's Pain would be torturous. On one occasion shortly before she discovered the benefits of cannabis, ANGEL's Pain levels were so high for such a prolonged period of time that, her body and soul racked with agony, ANGEL attempted suicide—as a desperate attempt at the only escape she could perceive from her torment.

A. ANGEL's numerous Pain conditions, as with all her medical conditions, exhibit a complicated interplay between each other, whose exacerbation presents the potential of a vicious spiral. Those Pain conditions include:

B. *Scoliosis*: ANGEL is plagued with abnormal curvatures and a rotation of the spine in her upper back and neck. She will be afflicted with Scoliosis until the day she dies. Scoliosis causes Chronic Pain in the vertebrae and muscles around her spine. The constant Pain ANGEL experiences from Scoliosis also causes or

exacerbates other medical conditions by affecting the musculoskeletal system of the arms, ribs, shoulder, clavicle, neck, and jaw. In addition, the painful site of a recent neck and back injury causes excruciating burning Pain in her vertebrae, nerve problems going down both arms, and difficulties with her thumbs. The injury also caused several of ANGEL's other Pain conditions to worsen. The resulting Pain has caused ANGEL to experience multiple episodes of Seizures and Muscle Spasms (which are painful in their own right) further exacerbating ANGEL's other Chronic Pain conditions and causing new and painful secondary injuries. Perhaps most critically, the injury caused ANGEL to get Fibromyalgia, a pain and fatigue disorder.

C. *Temporomandibular Joint Dysfunction Syndrome (TMJ):* TMJ combined with Bruxism causes pain, aching, throbbing, soreness, spasming, or cramps in ANGEL's face, gums, teeth, and jaw. This can make it difficult to talk, can make her jaw lock closed, can make eating difficult, and can cause headaches. Medical cannabis helps release ANGEL's cramps, relax her muscles, open her mouth, and cope with the Pain. Without medical cannabis, ANGEL's TMJ and Bruxism would spin out of control, worsening her Weight Loss conditions.

D. *Endometriosis:* Endometriosis causes ANGEL to experience disabling excruciating pain, and light headedness due to blood loss, during menstrual periods. ANGEL has undergone seven surgeries for Endometriosis. Immediately following her most recent surgery, ANGEL vaporized with cannabis in the hospital, amazing her doctors and nurses with how fast she recovered relative to patients who use narcotics after surgery.

E. *Headaches*: ANGEL experiences extremely Painful Headaches all over her head. ANGEL wakes up with Headaches nearly every morning. If they are too overpowering she must retreat to a dark quiet place. The muscles in her head and face can go into spasms, exacerbating the Headaches. Vaporizing or smoking cannabis helps ANGEL with Headaches that are not too bad, but the only medication that helps her with Severe Headaches is eating cannabis food.

F. *Rotator Cuff Syndrome*: A work-related injury in 1986 caused ANGEL to get Rotator Cuff Syndrome. Its Burning Pain has worsened over the years. She has difficulty doing repetitive tasks with her right arm, hand, shoulder, and shoulder blade. Overdoing them can cause her shoulder to freeze up and excruciating Burning Pain. Medical cannabis helps ANGEL cope with the Pain, and cannabis makes muscles, tendons, and ligaments around her shoulder joint more pliable, allowing her to use her arm.

G. *Uterine Fibroid Tumor*: ANGEL has a Fibroid Tumor within or on the uterine wall. This causes extremely heavy menstrual bleeding, making ANGEL light headed, dizzy, and nauseous to the point of almost passing out. The heavy bleeding and Painful menstrual periods can keep ANGEL down flat on her back for two or three days per month. Medical cannabis helps minimize ANGEL's pelvic Pain and helps release Spasms and Cramps, allowing her to function more easily.

H. Chronic Pain combined with the Paralysis that confined ANGEL to a wheelchair made her feel that she suffered indescribable torture in Hell. Only medical cannabis, characterized by ANGEL as a miracle sent to her from heaven, delivered ANGEL from the pits of that Hell. Without cannabis, ANGEL would endure the

excruciating torture of Severe Chronic Pain, and she might even again attempt suicide in an effort to escape. Pain, Torture, and Death constitute irreparable harm.

55. *Post Traumatic Stress Disorder P.T.S.D.)*: Years of molestation, physical, and mental abuse by family members created traumas that left ANGEL with Post Traumatic Stress Disorder. Escalated raids by the Defendants on medical cannabis patients since 2001 have exacerbated ANGEL's P.T.S.D. symptoms: She can find herself uncontrollably overwhelmed feeling suddenly in danger, and consumed with feelings of fear, helplessness, and horror. She reexperiences past traumas, has nightmares, and becomes overwhelmed with anxiety. She is becoming increasingly upset, gets angry and aggressive feelings, and fears that she must defend herself before the federal government breaks in her door, attacks her, incarcerates her, or kills her. She experiences sensations of panic and of trying to escape, yet she is too sick and her body is too weak. Medical cannabis helps keep ANGEL from living in the past, helps her deal with flashbacks, and helps her have courage to face her past abuse, her anger, her sadness, and her hurt. Cannabis allows ANGEL to cope with and manage her P.T.S.D. symptoms in a calm safe manner. Experiencing traumatic events (such as learning of new raids by federal agents on medical cannabis patients) can still trigger the P.T.S.D.

56. *Non-Epileptic Seizures:* When ANGEL has a Seizure, she loses awareness, has uncontrollable movements of her arms or legs, shakes all over, and falls to the ground. If she forces herself to go about daily life while having functioning problems, if she moves too fast, or if she becomes frightened for any reason, she can have Seizures. They are extremely

Painful, make all of her Pain conditions worse, and can trigger several of her other conditions. She may suffer for days at a time, having series of Seizures in combination with excruciatingly Painful body jerks, muscle spasms, and twitches. The use of medical cannabis minimizes those symptoms. Medicating with cannabis at the first onset of symptoms can prevent a seizure.

57. *Fibromyalgia:* Fibromyalgia is a condition characterized by multiple serious conditions. It causes ANGEL widespread chronic Pain in her muscles, ligaments, and tendons. Every muscle in her body can scream out Pain. The Pain can overload her body, putting her flat on her back for days. Fibromyalgia also causes extreme fatigue, totally draining ANGEL of energy, as though her arms and legs are tied to concrete blocks, and making it difficult to concentrate. Fibromyalgia further causes a sleep disorder inhibiting deep levels of sleep, as if ANGEL spends nights with one foot in sleep and the other one out of it. Other Fibromyalgia symptoms ANGEL experiences include Premenstrual Syndrome, Painful periods, chest Pain, severe morning Stiffness, Cognitive Functioning Problems, Numbing in her arms and legs, Tingling sensations, muscle Twitching, Skin Sensitivity, Dizziness, Impaired Coordination, losing her balance, and stumbling. Medical cannabis makes ANGEL's muscles, tendons, and ligaments more pliable, allowing her to move and go about her life with her family. It also helps her cope with the Chronic Pain and makes physical therapy more effective.

58. *Inoperable Brain Tumor:* ANGEL has a Meningioma or Schwannoma Brain Tumor. The Tumor is too deep for surgeons to remove it. In research suppressed by Defendants, researchers found that THC

(one component in medical cannabis) slowed the growth of Cancer in Mice. Later research (conducted outside the United States) confirmed that THC can destroy Brain Tumors in rats. ANGEL's doctors want her to continue medicating with cannabis in the hope that, among its other benefits, it will prevent her Brain Tumor from growing.

59. *Paralysis*: In September 1995, ANGEL suddenly lost the use of her right leg. By 1996, ANGEL was paralyzed on the right side of her body. For two years, her doctors could not diagnose the cause of her paralysis or prescribe an effective treatment. They said ANGEL would never walk again. In 1998, the use of high quality cannabis allowed sensation slowly to return to ANGEL's right side. Finally, in 1999 ANGEL regained use of her arm and leg and eventually learned to walk again in a difficult process made possible by cannabis.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No.

ANGEL MCCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, AND JOHN DOE NUMBER TWO,
PLAINTIFFS

v.

JOHN ASHCROFT, AS UNITED STATES ATTORNEY GENERAL, AND ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION,
DEFENDANTS

DECLARATION OF FRANK HENRY LUCIDO, M.D. IN SUPPORT OF PRELIMINARY INJUNCTION

I, Frank Henry Lucido, M.D., declare as follows:

1. I am a physician licensed to practice medicine in California. I am Board Certified in Family Practice, and have been practicing general Family Medicine at 2300 Durant Avenue, Berkeley, California, since 1979. I have been on the Active Medical Staff of Alta Bates Hospital for over 20 years. I have also been the medical director of skilled nursing facilities. I have been Chairman of the Alta Bates Hospital Medical Education Committee, and a member of the Ethics Committee and the Family Practice Advisory Board. I was voted "Best Doctor in Berkeley" by the Daily Californian newspaper in 1993. Attached hereto is my Curriculum Vitae.

2. I am Angel McClary Raich's primary care physician, and have been coordinating her care with numerous medical specialists. Angel presents a complex and

complicated set of conditions. It is my opinion that Angel cannot be without cannabis as medicine because of the precipitous medical deterioration that would quickly develop.

3. Angel is seriously ill. Her medical records confirm that she has numerous serious medical conditions, including life-threatening weight loss, nausea, severe chronic pain (from scoliosis, temporomandibular joint dysfunction and bruxism, endometriosis, headache, rotator cuff syndrome, uterine fibroid tumor causing severe dysmenorrhea, chronic pain combined with an episode of paralysis that confined her to a wheelchair), post-traumatic stress disorder, non-epileptic seizures, fibromyalgia, inoperable brain tumor (probable meningioma or Schwannoma), paralysis on at least one occasion (the diagnosis of multiple sclerosis has been considered), multiple chemical sensitivities, allergies, and asthma, and her body reacts with violent side effects to almost all pharmaceutical medications.

4. Angel will suffer imminent harm without access to cannabis. Chronic severe pain constitutes harm. Nausea and anorexia resulting in weight loss, risking malnutrition, cachexia, starvation, and death, constitute harm. Untreated seizures constitute harm. Post-traumatic stress disorder, inadequately treated, constitutes harm. Angel needs to medicate every two waking hours. If she misses a treatment, it could quickly have dangerous repercussions for her health. She clearly loses weight, and would risk wasting syndrome and death, without cannabis. No one knows why she can't hold onto her weight. Angel could become gravely ill if she loses too much more weight. Angel becomes debilitated from severe chronic pain. The pain is bad enough

even with cannabis, but it flares up immediately and becomes unmanageable without cannabis.

5. There are several studies concluding that cannabinoids may have significant anti-tumor activity. I feel that Angel should continue medicating with cannabis in the hope that, among its other benefits, it will prevent her brain tumor from growing.

6. Cannabis works well for Angel in a way that no other medicine has or can be expected to in order to alleviate Angel's medical conditions or symptoms associated with them.

7. Angel has no reasonable legal alternative to cannabis for the effective treatment or alleviation of her medical conditions or symptoms associated with the medical conditions because she has tried essentially all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects. Angel has tried all of the following medications, which all resulted in unacceptable adverse side effects:

Marinol
Demulen Tablets
Codeine
Tylenol #3
Erythromycin
Acetaminophen with Codeine
Serzone
Amitriptyline
Clonidine
Meclizine
Promethazine
Depakote
Prazosin
Carbamazepine

Imipramine
Trazodone
Methadone
Hydrocodone
Dicloxacillin
Chlorpheniramine/Phenylpropanolamine
Beclonmethasone
Vicodin
Dilantin
Tagretol
Desipramine
Valproic Acid
Seldane
Lorazepam
Paxil
Lamotrigine (Lamictal)
Elavil
Soma
Albuterol Solution
Fentanyl
Versed

Most of the medicines listed above, and others not even listed, make Angel vomit violently. Other side effects of the above medications include hot and cold flashes, shakes, diaphorasis, itching, nausea, and drowsiness. In addition, Marinol caused rapid heart palpitations, dizziness, shaking, and insomnia. Diagnostic lumbar tap and sympathetic block and stellate ganglion block in the throat have been performed with no lasting benefit. After a certain number of medications have been tried, it would be malpractice to subject the patient to further unnecessary harm.

8. Angel's medical records confirm that she uses two and one-half ounces of cannabis per week, in various forms, including oral ingestion, smoking, vaporizing, and topical application. There are no other treatments that I can reasonably recommend for Angel, other than what we are already doing in her course of treatment. It could very well be fatal for Angel to forego cannabis treatments because of a law that may purport to prohibit the medical use of cannabis.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on this 29th day of October, 2002, in Oakland, California.

/s/ FRANK H. LUCIDO, M.D.
FRANK H. LUCIDO, M.D.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No.

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v.

JOHN ASHCROFT, AS UNITED STATES ATTORNEY GENERAL, AND ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS

DECLARATION OF DR. JOHN ROSE IN SUPPORT OF PRELIMINARY INJUNCTION

I, John Rose, declare as follows:

1. I am a medical doctor, duly licensed to practice in the State of California, and have been so for 29 years. My practice is located at Brownsville and Yuba City, California. My practice consists of general family medicine. I am a board certified specialist in Family Practice. I am on the Medical Staff of Fremont and Rideout Hospitals. I am also Vice-President of Sutter North Medical Group. Attached hereto is my Curriculum Vitae.

2. I have been the personal physician and family doctor for Diane Monson for nine years and am completely familiar with her medical condition over those years. I have coordinated her care with various other medical practitioners.

3. As indicated from her medical records, Diane suffers from a number of medical conditions. She has degenerative disease of the spine. As a result of her medical condition, Diane Monson suffers from Chronic Back Pain and Spasms.

4. In 1999, pursuant to California State law, medical cannabis was recommended for Diane as treatment of her medical conditions, including her Chronic Back Pain and Spasms. I have determined that Diane Monson's health benefits from such a recommendation, that medical cannabis use is deemed appropriate for Diane Monson, and that medical cannabis provides necessary relief for Diane's pain and suffering.

5. Although Diane has tried other medical alternatives to medical cannabis, including Flexeril, a muscle relaxant, and Feldene, a powerful anti-inflammatory, those prescription drugs have proven to be either ineffective in relieving Diane's pain and suffering or produce intolerable side effects. In addition, these prescription medications have long term effects that may prove to be harmful to Diane's physical well-being.

6. I have also prescribed Vicodin and Vioxx to attempt to alleviate Diane's pain and suffering. Yet, Vicodin, an addictive drug, seems to have a nauseating effect upon her and I have recommended that she avoid it because of the extremely sick stomach that it leaves her with for several days after any use. In addition, Vioxx, although it appears to relieve Diane's inflammation associated with her back pain, does not relieve her painful spasms.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and

correct, and that this declaration was executed on this 29th day of October, 2002, in Brownsville, California.

/s/ JOHN B. ROSE, M.D.
JOHN B. ROSE, M.D.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No.

ANGEL MCCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, AND JOHN DOE NUMBER TWO,
PLAINTIFFS

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JOHN ASHCROFT, AS UNITED STATES ATTORNEY GENERAL, AND ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION,
DEFENDANTS

DECLARATION OF DIANE MONSON IN SUPPORT OF PRELIMINARY INJUNCTION

I, Diane Monson, declare as follows:

1. I am 45 years old and for last 24 years I have lived in the city of Oroville, located in Butte County, California. I am one of the Plaintiffs in the above-entitled action.

2. I am a medical cannabis patient, and have been since March of 1999. I use medical cannabis on the recommendation of my physicians for the treatment of my Severe Chronic Back Pain and Spasms, which have plagued me since 1989. Dr. Rose has been my personal physician for many years and is completely familiar with my medical condition.

3. The constant spasms with which I suffer, and which are related to, and caused by, my chronic back pain, are an extremely painful experience in their own right, comparable in intensity to an uncontrollable

cramp. Cannabis completely eliminates these spasms as no other substance has been able to do. Without cannabis, these spasms would be torturous and unbearable no matter whatever other medications were available.

4. I have tried numerous prescription and non-prescription drugs for my Severe Chronic Pain and Spasms, including Flexeril, a muscle relaxant, and Feldene, a powerful anti-inflammatory. From the beginning those drugs caused me significant problems. Flexeril has a very powerful effect on me and makes me groggy in any amounts, even if I halve the recommended dosage. If I take the prescribed dosage, I inevitably fall asleep and am unable to function as a normal human being. Flexeril has been ineffective in relieving my spasms and also has many undesirable side effects. In addition, I am quite concerned about its effect on my organs, including my kidneys and liver, over the many decades of necessary use, even if it were effective in relieving my pain.

5. The other drugs I have had prescribed over the years are Vicodin and Vioxx. Vicodin, an addictive drug, has a complete nauseating effect upon me and I avoid it because of the extremely sick stomach that it leaves me with for several days after any use. Vioxx is supposed to be easier on the stomach, so I take it occasionally to reduce the inflammation associated with the back pain. Regardless, it does not relieve the spasms.

6. I am employed as the office manager for one business and the bookkeeper for several other businesses as well. Inevitably, the stress levels with these responsibilities rise throughout the day. The more stress I have, the worse the back pain is. I have sought out various methods of self-help in dealing with my pain

and suffering, including exercises, long walks, yoga and stretches, which I do each and every night. I am keeping my weight down and eat a healthy diet. I walk a very hard mile and a half per day, which helps to strengthen the back muscles as well. Regardless of this regimen, my chronic back pain and spasms generally start by late morning each day; when the yoga and walking that I do earlier that day wear off. From that point in the day forward the pain worsens by the hour. Before I began using medical cannabis I was having back spasms multiple times per week. Once a spasm starts it is very difficult to relax my back enough to make it stop. Generally speaking, work is impossible during spasms, sitting down is impossible, and the only way to even partially relieve the severe pain it causes is to lie down altogether.

7. In early 1999, when I first tried cannabis for my back pain and spasms, I immediately noticed a massive improvement in my level of pain. And from the moment I began to use medical cannabis my spasms decreased in frequency about 75 percent. The medicine relaxes me without making me sleepy, and so I can work again without pain. I still do most of the self-help things I have been doing for years, and now I have added medical cannabis to my self-help list. In addition to the smoking method, I use a vaporizer for the cannabis. My physicians recommended the vaporizer. Another delivery method I have used with cannabis is a sublingual spray form. This is a method I use in a more crowded situation, where other people might object to the smoke from my medicine.

8. In early 2002 I elected to stop hormone replacement therapy. I had taken HRT for nearly 14 years at that time and I began to worry about the side effects of

that medicine and the recently reported risks associated with such use. But I had no idea of the effect that quitting would have upon my body and my psyche. The physical symptoms were fairly intense, with hot flashes and trembling hands. The mental repercussions were even more debilitating. I became anxious and had a hard time concentrating. Tears would come easily for little to no reason. Although I have always sought out new clients and work, I was overwhelmed by responsibilities and sought no further clients. I have to say my self-confidence plummeted in those first few months after ending my hormone replacement therapy. I then discovered that cannabis helped me through this stage in my life, too. While contemporaries are being prescribed Paxil and Prozac and other drugs to help with these menopausal symptoms I rely on cannabis to calm my psyche and alleviate the symptoms. Its effect upon me is soothing and I find that cannabis alleviates the physical symptoms as well.

9. With regard to all of the above symptoms and medical conditions, I have found medical cannabis to be both effective and free of undesirable side-effects. Cannabis virtually eliminates my debilitating and extremely painful Spasms and greatly relieves my Chronic Back Pain. Without cannabis, my spasms would return and I would be subjected to intense pain that cannot be relieved any other way. I have tried various combinations of prescription pharmaceutical medications, but they are often ineffective and they always disrupt my quality of life by interfering with my ability to function.

10. On August 15, 2002, deputies from the Butte County Sheriff's Department and DEA agents visited our home. After a discussion with them, the sheriff's

deputies agreed that my cultivation and possession of six cannabis plants was lawful under the Compassionate Use Act of the State of California. The DEA agents insisted on seizing and destroying my plants. For three hours we talked with them, reasoned with them, and finally pleaded with them to leave the plants alone. The local District Attorney, Mike Ramsey, also fought for my right to keep my medicine by calling John K. Vincent, the U.S. Attorney for the Eastern District of California, to plead with him to keep the DEA agents from destroying my medicine. All of the efforts by my local law enforcement agents and the Butte County District Attorney were to no avail. As I stood and watched, the DEA agents chopped down my medicinal plants. I was crying and my back began to tighten up; for the rest of the week I experienced debilitating back spasms. I have not had a good night's sleep since the actions of the DEA in destroying my plants. My 20-year marriage is suffering as well because my wonderful husband also has to deal with all the repercussions of this action. We do not feel safe; we have had our civil rights and our rights under California law taken from us in our own back yard. I must now find a way to get my medicine from another source. To do so will be very expensive and I will have no idea what the quality of the medicine I receive will be.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on this 29th day of October, 2002, in Oroville, California.

/s/ DIANE MONSON
DIANE MONSON

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No.

ANGEL MCCLARY RAICH, DIANE MONSON, JOHN DOE NUMBER ONE, AND JOHN DOE NUMBER TWO, PLAINTIFFS

v.

JOHN ASHCROFT, AS UNITED STATES ATTORNEY GENERAL, AND ASA HUTCHINSON, AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS

DECLARATION OF ANGEL McCLARY RAICH IN SUPPORT OF PRELIMINARY INJUNCTION

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I, Angel McClary Raich, declare as follows:

1. *Background:* I am a "medical necessity" medical cannabis patient. My medical records show I run a very real risk of malnutrition and starvation without the use of medical cannabis. I would starve to death without cannabis. I have been diagnosed with more than ten serious medical conditions including an inoperable Brain tumor, life-threatening wasting syndrome with severe weight loss borderline cachexia, a Seizure Disorder, Nausea, several Severe Chronic Pain Disorders,

including Scoliosis, Temporomandibular Joint Dysfunction Syndrome, Bruxism, Endometriosis, a Tumor in my Uterus, and other documented medical conditions. My medical conditions are very complicated, complex, and difficult to manage. I am blessed to have a great primary care doctor and many dedicated specialists and extensive medical records. I have been permanently disabled since September 1995. I am a mother of two children. My son is 16 and my daughter is 14 years old.

2. I have been using cannabis as a medication for about five years, every two waking hours, every day, and I have not been adversely effected by my medical use of cannabis—just the opposite. On a good day if you were to see me face to face you may not even know I am disabled. I do not enjoy being disabled nor do I like taking medication every two hours, but I have no alternative. Medical cannabis keeps me alive and greatly reduces my suffering. I can not use Marinol pills; because of my extreme drug sensitivity, I am just not able to take them. Only the natural cannabis plant works for me.

3. I was in a wheelchair from January 1996 to August 1999 because of my many medical conditions and their debilitating effects on my body. In 1997 before the use of cannabis I was debilitating quite fast. All of my doctors were not getting anywhere with my treatment and nothing seemed to work, but by August of 1999 I was walking again because of medical cannabis. Cannabis was responsible for getting me out of my wheelchair and restoring my mobility on the whole right side of my body.

4. I had complications taking nearly every type of synthetic medication my doctors prescribed. Practically every single medication my doctors gave me

would make me extremely ill, causing me to vomit violently, sometimes for 24 hours. I had allergic reactions and chemical sensitivities to nearly all of the medications my doctors prescribed. For example, I am allergic to all narcotics and opiates. When I take any narcotic or any opiate, within about 20 minutes I am on the floor with my face in a pan or small trash can violently vomiting, I get the shakes, hot and cold flashes, and insane itching that nothing can stop. Being partially paralyzed on the floor, it was Hell. I could not hold myself up. I sometimes needed someone to hold up my head while I was vomiting. I was simply too weak to move.

5. By 1997 my doctors told me I would never walk again and that they could not control my pain. My medical conditions were triggering each other as I became increasingly worse. That is when my doctors and I started talking about medical cannabis as a medication to help alleviate my pain and suffering.

6. My specialists do not know why I can not hold onto my weight. In 2000, my wasting syndrome was out of control, becoming life-threatening and causing my weight to drop to only 94 pounds. My health—even my life—was at great risk. My doctor worked quickly to raise the levels of cannabis in my bloodstream. Every time my level of cannabis drops, I can lose as much as one pound per day. My doctor says I must never be without cannabis treatments. I will always have to fight to keep my weight balanced; however, without cannabis it would make that fight impossible.

7. I suffer greatly from pain every single day. The prolonged pain and suffering from my medical conditions significantly interferes with my quality of life. I have not been pain-free for several years, but at least I

am not in a wheelchair anymore thanks to medical cannabis. My experience is that cannabis allows me to combat all of my diseases daily and gives me the strength I need to fight to stay alive.

8. The hardest part of being disabled is watching the suffering in your children's eyes as they watch you endure such suffering with no end in sight. They experienced great joy knowing that cannabis was responsible for giving their mommy back to them. Cannabis saved my life and gave my children their mother back. I would rather use cannabis to end the suffering from my conditions, and be alive, than to suffer endlessly while I die knowing that there *is* something that could help treat my conditions.

9. It may be difficult for the reader to comprehend the amount of intense pain and suffering described herein. When you become disabled one of the most difficult things is accepting that you are disabled and life as you knew it has ceased to exist. Your life changes forever from that moment on. When you are told you are *permanently* disabled it is even worse. Being permanently disabled has been very difficult for me to deal with, day in and day out, year after year. It is equally difficult for my family. As I fight to stay alive every day, my biggest challenge on a daily basis is combating my diseases, trying to minimize my suffering, and at the same time doing my best not to go into "overload" from excruciating pain. I do the best I can while remembering to have compassion for all life, and keeping my dignity and my grace. I am finding it a challenge to have compassion for the United State Government, when the Government wants to sentence me to death for being disabled and fighting to use a plant that is saving my life. I am weak and weary and

afraid of being raided, and I am afraid of what my death would do to my children and my husband. I am afraid of being tortured by being denied cannabis, and I am afraid of the excruciating pain that would cripple me while being forced to starve to death.

10. The Drug Enforcement Administration (DEA) is attacking sick, disabled, and dying Americans. Since September 11, 2001, the DEA has continued raids on the California medical cannabis community. The DEA has been terrorizing and doing harm to other patients using cannabis. This is creating great fear for me and my children. I am just fighting for my life. I promised my children I would fight to stay alive and I am not about to go back on that promise.

My Medical Conditions, Symptoms, and the Stories Behind My Suffering:

11. I will do my best to explain all of my complicated medical conditions starting in my childhood. The time period between 1995 and 1999 is the most difficult and is very painful to explain. All of my doctors knew I was seriously ill and suffering from severe pain. The doctors became frustrated because they could not figure out what was happening to the right side of my body. My doctors kept changing my diagnoses while trying to unlock the mysteries to why my health was failing, only to end up with more questions than answers. Many doctors told me that I was too complicated for them to understand, that they could no longer help me, and then referred me to another doctor. I had too many medical conditions affecting me the same time.

12. *Post Traumatic Stress Disorder (P.T.S.D.):* From the age of four years old to when I was in the six grade my grandfather repeatedly molested, threatened,

imprisoned, and tortured me. My doctors say that my grandfather was one of the worst child molesters on their rating scale. My grandfather was just below the child molesters that kill children. I was physically and mentally abused by other family members throughout my lifetime. I have worked very hard throughout my life to heal my wounds by getting the help I needed, and by being a good mother and a good citizen who obeys the laws. It was a long road, and I fought hard to keep abusers out of my life. I was diagnosed with P.T.S.D. in 1987.

13. Since the Federal Government escalated its raids on California medical cannabis patients, I have been experiencing more intense P.T.S.D. symptoms. I find myself overwhelmed feeling suddenly in danger, and I have become consumed with feelings of fear, helplessness, and horror. The constant threat I feel is making me re-experience my past traumas. It is causing me to feel the same mental, emotional, and physical experiences that occurred during the past traumas. This includes thinking about my past trauma and the threat of losing my life. For the past year I have been experiencing the following symptoms due to the threats and attacks from the United States of America's war against cannabis patients: I get bad dreams and nightmares of being attacked and killed by the federal government. I am also having flashbacks and nightmares of being unsafe and unprotected. Every time another patient or provider is raided, I am overwhelmed with anxiety and fear of being in danger, wondering if I will be the next patient to be attacked. I am deeply concerned about my own health and safety. I become increasingly more upset every time I am reminded about the trauma we patients face at the

hands of our own federal government. I get real angry and aggressive feelings because I feel that I have to defend myself before the federal government breaks in my door, attacks me, incarcerates me, and kills me. My brain can not handle any kind of trauma. I feel the trauma is happening again, only now it is the federal government abusing me. I feel as if I am in danger. I experience sensations ot panic, and trying to escape, and of thinking about attacking first, yet I am too sick and my body is too weak. These experiences are not voluntary; no matter how hard I try, I usually can not control them or stop them from happening. I am just as innocent now as I was when I was a child because I am sick, disabled, and fighting to stay alive. I had my P.T.S.D. symptoms pretty much under control until the federal government started escalating its raids against California cannabis patients. Cannabis helps keep me from living in my past, helps me deal with flashbacks, and helps me cope with the P.T.S.D. symptoms being brought on by the federal government's actions against medical patients. It helps me have the courage to face my past abuse, the feelings of never being safe or protected by anyone, my anger, my sadness, and my hurt in a calm safe manner. Cannabis allows me to cope, and manage my P.T.S.D. symptoms.

14. *Scoliosis:* Scoliosis is a curvature of the spine. My first diagnosed medical condition was Scoliosis. I was in the seventh grade when it was diagnosed. The doctor said my back is shaped as a backwards "S" and my spine is twisted and rotated. The doctor said that if my spine were rotated two more degrees he would have had to do surgery and put a steal rod into my back, but instead I had to wear a back brace for three years. This was my first experience with chronic pain. The chronic

pain in my back has never gone away, still to this day. In fact, as the years go by the chronic burning pain has become more intense and more difficult to tolerate. I experience burning pain in my back muscles and around my vertebrae. I learned at a young age how difficult it can be to be a handicapped person and how mean people can be to the disabled. While I was wearing my back brace children and adults made fun of me. I lost all of my friends, and no one wanted to hang around me anymore, just because I was in a back brace. It made my seventh through ninth grade years of school very lonely. I was not able to do much of anything; I was hurt, embarrassed, and in chronic pain. I could not even turn my head because the brace came up under my chin and went down to my tale bone. The brace was very painful. I remember crying all the time.

15. For years, my scoliosis has given me prolonged chronic pain in my spine that interferes with my quality of life. It also affects my mobility daily. One part of my spine is constantly moving, making loud painful cracking noises. Another part of my spine locks up, which is extremely painful. When this happens my neck, jaw, collar bone, shoulder, and rib cage lock-up tight, preventing me from moving freely and creating an unstable body structure. In that condition moving my body creates severe chronic pain and excruciating chronic burning pain in my neck, jaw, back and sides, ribs, and down my right arm. Staying still is equally painful. Without cannabis my tendons, and ligaments feel like an over-stretched rubber band about ready to snap. Cannabis makes my muscles, tendons, and ligaments more pliable, allowing my body to move and go about my daily life. Cannabis allows me to cope with the severe chronic pain and burning every movement

brings to my body. I notice a big difference when eating cannabis before going to physical therapy, it helps relax my muscles, making it easier for my physical therapist to help relieve some of the pain and burning and unlock my vertebrae and my other joints.

16. *Endometriosis:* Endometriosis come from the word "endometrium," which is the tissue that lines the inside of the uterus and builds up and sheds each month in the menstrual cycle. In Endometriosis, tissue like the endometrium is found outside the uterus, in other areas of the body. These growths cause disabling chronic pain, scar tissue, and other problems. Just before I turned sixteen years old I was diagnosed with endometriosis and my doctor told me to go home, pack a bag, and meet him at the hospital because they had to do surgery. My endometriosis was out of control. I was in excruciating pain and the cramps made it hard to move around. During the first two days of my period each month I was not be able to move at all. I had to stay down. I would curl up in a tight ball and cry for hours. In my second surgery for endometriosis the doctors not only found the endometriosis, but they also found several cysts. By the time I was 21 years old I had already had three surgeries for endometriosis. Through the years my endometriosis has changed, and the operations become more complicated. Every time they open my stomach up they risk damaging my organs, it makes it more difficult to work around the scar tissue. About every four to five years I must have surgery for endometriosis and scar tissue. I can always tell when it is time for surgery because my periods become overloaded with pain, I am no longer able to move around, and I can't move my legs to walk. I become paralyzed from the excruciating pain and I

bleed so heavily that I become light-headed from such fast blood loss. The pain can cause me to have seizures. To date, I have had seven surgeries for endometriosis, and with six out of the seven I woke up in the recovery room violently vomiting. The drugs made me vomit very violently, sometimes for over 24 hours, and after just having surgery vomiting is extremely painful. In 2001 my pain from endometriosis again became so severe that I was in tears. I had surgery in November 2001. The hospital gave me a room on the oncology floor so I could medicate with cannabis, using my vaporizer in the hospital promptly after coming out of recovery. Most patients after having surgery can have a narcotic or opiate. When I got back to my room after surgery I was so weak, I was not able to prepare my cannabis or my vaporizer. A family member helped me by holding up my vaporizer while I medicated with cannabis. The nurses at the hospital all asked about the medical cannabis and how well it helped my medical conditions, and they wanted to see me vaporize with cannabis. My doctor told me I recovered faster with cannabis than the patients who use narcotics or opiates. The doctors and nurses were all amazed because they got to see how effectively cannabis works right before their eyes.

17. *Rotator Cuff Syndrome:* After my son was born in 1986 I went back to work in a lumber mill where I became seriously injured working at a glue machine. I could not move my right shoulder. I was in tears and in extreme pain and muscle spasms. I was taken to the hospital where I was diagnosed with rotator cuff syndrome. After having it for many years, the chronic burning pain is worse than when I was first injured. I went to therapy for months until I was sent to another

specialist who gave me five sessions, of five shots each, of cortisone in my right shoulder and my neck. The cortisone helped for about three years, then the excruciating pain returned. My right shoulder never went back to normal. I have problems doing anything repetitive with my right arm, hand, shoulder, or shoulder blade. I suffer from excruciating burning pain, my shoulder freezes up, and I loose the mobility in my shoulder. It is cannabis that allows me to gain back some of this mobility. Through the years I have also had several injuries to my right shoulder (See paragraph number 18.). Cannabis makes the muscles, tendons, and ligaments around my shoulder joint more pliable, allowing me the use of my right arm. Cannabis allows me to cope with the severe chronic pain and chronic burning associated with rotator cuff syndrome. I noticed a big difference when eating cannabis before going to physical therapy; it helps relax my muscles making it easier for my physical therapist to help relieve some of the chronic pain and burning and unlock my shoulder and my shoulder blade.

18. *Other Past Spinal Injuries:* The year of 1991 was a bad year for me. I was in three accidents in a two month time period. All three accidents injured my spine and the right side of my body. I slipped and fell, injuring my spine on the right side; I was rear-ended by a big truck, injuring my back, neck, pelvic area, and bladder; and then a car hit me while I was walking, injuring the right side of my body again. It was all very painful and my body did not heal as fast as it should have. I had to see a chiropractor and a physical therapist for months. My body is extremely fragile and it does not heal easily, so I do a lot of suffering. Having injury upon injury caused permanent damage to my

body structure. I have continued to endure constant chronic pain and chronic burning ever since.

19. *Multiple Chemical Sensitivities, Allergic Reactions, and Asthma:* My treatment is complicated by the fact that I am violently allergic or I have severe multiple chemical sensitivities to almost all pharmaceutical medicines. This interferes with the treatment of all of my medical conditions, and it means my suffering can not be controlled by synthetic medications. This makes it extremely difficult for my doctors effectively to help me combat my diseases. I have problems with asthma and allergies, which make me wheeze and cough from the lack of air. I also have problems with chemicals that are in many skin products, air fresheners, perfumes, and detergents. I am not able to use pharmaceutical asthma medications and I am not able to take anything for my allergies. I become nauseated from most over-the-counter medications. So I just suffer. All of my doctors including my specialists have been supportive when it comes to my medical use of cannabis. I do not have any other alternative to battle my many complicated and complex medical conditions. Cannabis *is* maintaining my health. I am not just sensitive to synthetic prescriptions, I am also chemically sensitive to things such as chemicals that some cannabis growers use. These additives are not harmful to most patients; I am just extremely sensitive.

20. *Severe Chronic Pain:* Every second I experience chronic pain in varied degrees, ranging from a medium level of pain to a complete overload of pain, brought on by one or a combination of the chronic pain conditions from which I suffer. When I am able to sleep it provides meager escape from the ever present chronic pain I experience. I have to force myself to do

everything, including getting out of bed every day. I wake up several times per night and rarely get a restful night's sleep because of the chronic pain. Because I have an extremely high pain threshold, I can occasionally function and still try to go about my life, even in the midst of experiencing pain. On frequent occasions, however, the chronic pain becomes so great that I experience difficulty performing everyday activities, or the chronic pain is so overpowering that I become completely debilitated and cannot get out of bed. Then I am usually down for a few days.

21. When my nervous system becomes too overloaded with pain I experience muscle spasms and seizures. My treatment is complicated by the fact that I am violently allergic to almost all pharmaceutical medicines. Cannabis, however, has the effect of making it easier for me to tolerate my constant chronic pain, although it does not make the pain go away. The efficacy of cannabis is well established as an analgesic. Cannabis is the only medication that keeps me alive and makes my severe chronic pain more manageable. Without cannabis, my chronic pain would be even more torturous.

22. *Paralysis:* Due to all of the traumatic events in my life, in 1995, one last traumatic event caused my brain shut the whole right side of my body down for years, leaving me in a wheelchair until late 1999. I was barely hanging on because of all the pain and suffering I was forced to endure. It took many years and many doctors to diagnose all of my medical conditions, and I was suffering unexplainable, excruciating pain. My doctors were giving me many different kinds of prescription drugs; these same prescription drugs were making me vomit violently. My health continued to

spiral downward, leaving me with no hope at all. Months went by. After feeling that my doctors were not helping me I changed doctors once again. Even though I felt like I was drowning in pain, I kept the promise I made to my children that I would never give up again. I was going to do whatever I had to do, to get well and become healthy, or as healthy as I could be given my medical conditions. A new doctor sent me for a brain MRI in May 1999. It showed I have a one centimeter brain tumor on the left side of my brain, adding yet another physical medical condition. My doctor also sent me for an EEG, which showed I was having seizures. Then my doctor sent me to the Stanford University Hospital Epilepsy Center and a brain tumor specialist. Because I was not able to use the right side of my body and I was having cognitive functioning complications. During this same timeframe I was once again diagnosed with Post Traumatic Stress Disorder.

23. The use of cannabis was responsible for getting me out of my wheelchair. After I began using cannabis in 1997 I started feeling nerve sensations in my body. I stopped using cannabis from off the street in 1998. I started to get better from the medicine I obtained from the Oakland Cannabis Buyers' Cooperative. The better quality cannabis made all the difference in the world. The sensation slowly started coming back into my right side. I was so happy, I really wanted to walk again. By August 1999 I was able to move my right arm, toes, ankle and my foot. Then I was able to make small movements in my toes and fingers, and eventually I was walking again. Learning to walk again was very difficult and painful. Without cannabis being continually in my body I would surely become wheelchair bound

once again; this possibility is very frightening to me and my family.

24. Cannabis has given me faith, hope, happiness, better health, and family. It helps tone down my pain and suffering, not to mention: it keeps me alive. Cannabis proved to be the only medicine that brought back feeling in the right side of my body and got me out of my wheelchair.

25. *Two Demulen Tablets:* In September 1995, three days before I lost feeling from the waist down, I went to a new doctor regarding my severe endometriosis pain and complications. It was really time for me to have surgery again for my endometriosis. The doctor did not want to give me surgery, instead she wanted to put me on birth control pills to control some of the symptoms. I explained to her that I was allergic to all forms of birth control pills. The doctor told me that just because I was allergic to a drug when I was a teenager and in my early twenties did not mean I was still allergic it. I took the pills on the advice of my doctor and I have been paying for that ever since. After taking just two Demulen pills, my health was taken away forever.

26. I became permanently disabled in September of 1995. My chronic pain condition became complex right from the start. I was at work when all of the sudden I felt a strange sensation go down my leg. In a matter of moments, my right leg was like Jell-O, bright red, and cold as ice. I could not walk on my right foot because my ankle was so weak it would fall to the side. I was taken straight to the doctor. I was quite afraid because I could not feel my body from the waist down on the right side of my body. The next day I was dragging my leg around and I was unable to stand. Fear raced

through my body and tears came from my eyes. The severe chronic pain I was experiencing was putting me in a world of pain and suffering, and making my life a living hell and my doctors' jobs extremely difficult when it comes to treating any one of my medical conditions.

27. The chronic pain I was experiencing caused me to become partially paralyzed on the right side of my body from the waist down and I was unable to use my right leg. My scoliosis and my endometriosis made things even worse for me. I did end up having surgery for my endometriosis and scar tissue six weeks after I took the birth control pills. It is extremely difficult for me to battle the physical manifestations of chronic pain and my nervous system is very fragile. I experience complications when my chronic pain conditions trigger each other, which makes all of my symptoms worsen.

28. *Suicide Attempt:* In August of 1997, shortly before I discovered the benefits of medical cannabis, my chronic pain levels were so high for such a prolonged period of time that, my body and soul racked with agony, I attempted suicide—as a desperate attempt to end the excruciating pain and my suffering. I was drowning in chronic pain for years, it was the only escape I could perceive from my torment. The lack of sleep effected my thinking process, until my brain was foggy and I could not see past the excruciating pain. I could not live another day with that kind of chronic pain, which nothing was helping. I was lost, I lost my faith, I lost my will, and I lost any hope I had left. I just could not handle the torture from the chronic pain anymore. I am blessed to be alive today, for I have been given a second chance at life. That night I made a promise with God that I would do God's work if He

gave me back my legs, and I promised to do my best not to complain about the chronic pain if God would helped me find something to help ease the pain. A couple of weeks later, a nurse who had been watching me suffer asked me if I had ever thought about using medical cannabis. I was offended because I was not in support of marijuana use. My doctors could not figure out what had been wrong with me for over two years. At the time I was in a wheelchair and partially paralyzed on the entire right side of my body. I wanted my suffering to end as soon as possible. I was becoming sicker and sicker from the prescription drugs the doctors were pumping into me, only to vomit the pills up prescription after prescription, until the cure was worst than the disease. I felt hopeless and I just wanted my suffering to end.

29. My numerous chronic pain conditions, as will all my medical conditions, present a complicated mosaic of problems with a confusing interplay between each other, exhibiting the potential of a vicious spiral that exacerbates all of my medical conditions. When I first started experiencing extreme levels of chronic pain I did better at hiding my pain and not letting the pain show on my face. Year by year it gets harder and harder to hide the chronic pain my body feels because pain takes over my body. Then there are the days I just can not get out of bed at all except to go to the bathroom. The chronic pain keeps me down until my body stops burning, throbbing, cramping, and my muscle spasms go away. I am tortured by chronic pain of all different kinds. It turns out to be a never ending circle of chronic pain. The chronic burning pain that goes on for days is the worst torture of all. It is hard to wake up every day and thank God for being alive, but I do

thank him everyday for giving me back my legs so I can walk. So I will do whatever I have to do to ease this excruciating pain and to fight to stay alive. I have to do it for my children, I have to do it for myself, and I have to do this for my husband. I love them all so much I want to be with them until I die of old age, not because the Federal Government raids me and puts me in jail where I could experience an even greater debilitating pain while I starve to death.

30. Dealing with high levels of chronic pain everyday for years becomes more and more difficult with each passing year. My body is deteriorating. I am a prisoner of my medical conditions and I am trapped in my body being made to live the rest of my life in severe chronic pain. Is not that enough? I will do whatever it takes to stay alive and as pain free as I can possibly be. When my nervous system becomes too overloaded with pain I experience muscle spasms and seizures.

31. *Muscle Spasms:* I regularly have muscle spasms that stem from my chronic pain. Spasms are sudden, involuntary muscular contractions, either of a single muscle or of a group of muscles. They are often very painful. Cannabis helps relax my muscles, making them more pliable, and it helps release my muscle spasms and cramps, allowing me to function more easily physically.

32. *Chronic Headaches:* I get very bad chronic headaches. They are extremely painful all over my head. The muscles on my head and face can go into spasms, causing excruciating chronic headaches making me find a dark quite place. Sometimes I get a bad headache just before I have a seizure. My headaches come from several of my medical conditions. Nearly every morning when I get up I have a headache. If my headache is not too bad I can get away with just vaporizing or smoking cannabis. When my headaches become overpowering, not even hours of being in a dark quite place helps. The only medication that helps my severe headaches is eating cannabis foods.

33. *Nausea:* I have chronic nausea that interferes with my quality of life. It makes eating and drinking difficult. My nausea can make my wasting conditions worsen when I am just not able to eat. When I eat I become even more nauseated, which makes forcing myself to eat a real battle. When I first started suffering from nausea my doctors tried me on several anti-nausea medications and a medication that was supposed to help me eat. The medications not only made me more nauseated but they also would make me vomit violently. If the cannabis levels in my bloodstream drop even just a little bit I can become extremely ill. Preventing and controlling nausea helps ensure that I am able to eat food properly. It is hard to eat properly when you feel nauseated all the time and when even the smell, sight, or taste of food can trigger the nausea, making it all worse. Sometimes after eating my stomach will cramp up leaving me in wrenching pain. However, without the use of medical cannabis I would be unable to eat at all and I would not be able to eat enough food to help me hold onto my weight. Cannabis helps moderate my nausea and stomach cramps, and helps me eat and maintain my weight, without adverse side effects.

34. *Severe Temporomandibular Joint Dysfunction Syndrome (TMJ) and Bruxism:* Temporomandibular Joint Dysfunction Syndrome causes facial pain. The temporomandibular joint (TMJ) is a gliding joint in the jaw. The syndrome hinders my jaw from opening and closing, which makes talking and eating difficult. My jaw can become tightly locked closed. When that hap-

pens the only way I can open my mouth is to force it open by cracking my temporomandibular joint, which is very painful.

35. Bruxism is forceful grinding and clenching of the teeth usually during sleep. The pressure that is generated across the teeth can be an incredible amount of force. Problems occur as a result of these forces being applied over many years.

36. Temporomandibular Joint Dysfunction Syndrome and Bruxism cause muscle spasms and muscle cramps that create severe chronic pain in my face and jaw muscles. Due to the Bruxism and TMJ, I am losing the bone and gum support in my mouth, and I am experiencing early periodontal problems. Because of these early periodontal problems, my dentist had to remove teeth in 1997, 1998, and 2001. I have two more teeth that are about to fall out. In effect my teeth have loosened because of the "rocking" back and forth. My bone, gums, and teeth ache and throb all the time and are very sore, and are sensitive to hot and cold. My mouth and jaw hurt all the time. Sometimes in the morning when I wake up I can't move my jaw and I can't chew. My whole face hurts and aches from the muscle spasms and the chronic pain. It becomes difficult to talk when my jaw locks up on me. Nothing helps the chronic pain go away completely. When the muscles in my jaw are overused they become sore and spasm. The spasms even make my neck hurt. I get chronic headaches from having TMJ and Bruxism. Cannabis helps release the muscle cramps and relax my jaw, face, and neck muscles in order for my temporomandibular joint to crack so I can slightly open my mouth to eat something soft. Cannabis allows me to cope with the chronic pain and burning in my jaw and

neck. Without cannabis being contentiously in my body I would not be able to relax the muscles around my mouth. Without the use of cannabis my TMJ and Bruxism would spin out of control, worsening my life-threatening weight loss, and rapidly causing malnutrition, starvation, and cachexia. For these reasons it is extremely dangerous for me to be without the use of cannabis.

37. *Life-Threatening Weight Loss, Malnutrition, Cachexia, and Starvation:* Since 1998, I have experienced great difficulty maintaining a healthy weight. My physicians, including my gastroenterologist, are unable to diagnose the root cause of my weight problems or to prescribe an effective course of treatment. One fact, however, is clear: I literally cannot eat without a sufficiently high level of cannabis in my system. Without cannabis, my weight can precipitously drop as much as one pound per day. As a five-foot four-inch tall woman, I dropped from 106 pounds to a dangerously low weight of 93 pounds during the course of four weeks in which I could use cannabis only on two weekends pursuant to a family court order (which was subsequently overruled due to my rapid health failure) in a child custody fight with my children's father. I struggle with Life-Threatening Weight Loss and Wasting Syndrome, a medical condition generally diagnosed as Anorexia/Cachexia meaning loss of appetite and rapid weight loss. (I do *not* have a better-known condition called anorexia nervosa, a psychiatric disease in which patients are obsessed with being thin and have an unrealistic body-image.) My body-image is accurate; I see how thin I am and I work extremely hard everyday to eat enough. I simply cannot eat without the aid of cannabis. I eat between 2500 and 3000 calories per day,

yet I have trouble getting my body to gain weight, for reasons that my physicians do not understand. The efficacy of cannabis is well established for stimulating appetite and promoting weight gain. The federal government claims cannabis has no accepted medical use and it claims cannabis is harmful to your health. Cannabis *is* safer than death. Without cannabis, I would run the very real risk of Malnutrition and Starvation. One result of Starvation is death. Dropping weight fast can become critical. Every time I have tried to cut my medical cannabis treatments back my weight dropped immediately. It is then difficult to bring my weight back up. This is how my doctors and I know that I require two and one-half ounces per week (equaling over eight pounds per year). Fighting to keep my weight up every single day is my biggest battle.

38. *Fibromyalgia Syndrome (FMS):* In 1997 I was first diagnosed with fibromyalgia. The symptoms slowly lessened, but then flared up again in early 2002. Fibromyalgia is a widespread musculoskeletal chronic pain and fatigue disorder that is often precipitated by physical trauma. Fibromyalgia means pain in the muscles, ligaments, and tendons—the soft tissue in the body. When my fibromyalgia acts up, my body feels extremely fatigued and every single muscle in my body screams out pain. When my body overloads with pain I will be flat on my back for days. The chronic pain keeps me down until my body stops burning, throbbing, cramping, and my muscle spasms go away. The best way I can describe it is "everything hurts". The chronic pain and the stiffness feel like a big diesel truck ran over my body, with the groups of muscles that are frequently used hurting most intensely. I also have neurological symptoms that are associated with FMS

and some of my other medical conditions. As mentioned, I get extremely fatigued. The best way I can describe the fatigue is that it is like a "brain fatigue" in which I feel totally drained of energy. It feels as though my arms and legs are tied to concrete blocks, and I have difficulty concentrating. I am unable to focus or make big decisions on the days I am overwhelmed by this brain fog. I have problems falling asleep and staying asleep due to my high levels of pain. Many FMS patients, including myself, have problems with deep levels of sleep. "Stage four" sleep is constantly interrupted by bursts of awake-like brain activity. I spend nights with one foot in sleep and the other one out of it. Other symptoms I have from FMS are premenstrual syndrome, painful periods, chest pain, severe morning stiffness, and cognitive functioning problems. Sometimes I have a numbing feeling in my arms and legs, tingling sensations, muscle twitching, skin sensitivity, dizziness, and impaired coordination. I also have problems with losing my balance and stumbling.

39. Without cannabis my tendons and ligaments feel like an over stretched rubber band about ready to snap. Cannabis makes my muscles, tendons, and ligaments more pliable, allowing my body to move and go about my daily life. Cannabis allows me to cope with the severe chronic pain and chronic burning every movement brings to my body. I noticed a big difference when eating cannabis food before going to physical therapy; it helps relax my muscles making it easier for my physical therapist to help relieve some of the pain and burning. Without cannabis being continuously in my body I would never be able to tolerate the burning and pain. My chronic pain levels become so high it

makes even my skin hurt, making it is very difficult for me mentally to be in my body. Cannabis rescues me from the torture I have to endure from fibromyalgia. When I go to bed at night my whole body may throb like a strong heart beat, making it impossible to fall asleep. Cannabis helps my fibromyalgia symptoms and allows me to have a life with my family.

40. *Non-Epileptic Seizures:* I started having non-epileptic seizures in 1996, though my doctors did not diagnosis the seizures until 1999. When I have a seizure, I can lose awareness, have uncontrollable movements of my arms or legs or both, shake all over, and fall to the ground. Between seizures I experience problems related to memory, language, mood, sleep, and other brain functions. I am able to feel my seizures as they are come on. Sometimes, I experience an extremely bad headache and/or a strange feeling in my throat just before I have a seizure. When I force myself to go about my daily life while I am having functioning problems, or if I move around too fast, or even if I become frightened for any reason, I can have a seizure. Because I have a brain tumor my seizure specialist at Stanford Epilepsy Center tells me that my seizures could turn into epilepsy. My seizures are extremely painful. Sometimes, I have one seizure after another. They can trigger several of my other conditions and make all of my chronic pain conditions worse. When this happens I usually suffer for days having a combination of more seizures, and I will have body jerks, muscle spasms, and twitches, which cause excruciating pain that are unbearable for me to deal with.

41. Non-epileptic seizures can be caused by many different factors, including impaired blood flow to the brain, sleep disorders, severe chronic pain, psychological disturbances, and various other brain disturbances. It is not uncommon to see this type of seizure in individuals who have experienced a traumatic event or who are under various types of stress. In my case I have had a lifetime full of traumatic events, one after another. I have also had my share of severe chronic pain.

42. Cannabis helps slow down and minimize body jerks, muscle spasms, and twitches and helps to control the excruciating pain caused by my seizures. If I smoke or vaporize cannabis at the first onset of seizure symptoms, the cannabis can prevent the seizure. If I am unable to use cannabis in time to prevent the seizure, I need to medicate with cannabis when I am alert enough to smoke or vaporize to prevent another seizure.

43. *Inoperable Brain Tumor:* In 1999 an MRI showed I have a brain tumor. I have a circumscribed one centimeter densely enhancing tumor in the left petrous apex that mildly deforms the ventromedial aspect of the left temporal lobe. It is a Meningioma or a Schwannoma brain tumor. My doctors say the tumor is too deep for them to do surgery to remove it.

44. My doctor wants me to continue medicating with cannabis in the hope that, among its other benefits, it will prevent my brain tumor from growing.

45. *Uterine Fibroid Tumor:* In 2001 I was diagnosed with having a uterine fibroid tumor. Uterine Fibroids are benign tumors of muscle and connective tissue that develop within or are attached to the uterine wall. They slowly enlarge, frequently intruding into the cavity of the uterus or growing out beyond the normal boundary of the uterus. Even one small fibroid

can cause many problems, sudden severe pain, and heavy menstrual bleeding. I have had several problems with my tumor in this past year. I suffer from sensations of fullness and pressure in my lower abdomen, severe pelvic cramping, abdominal fullness, and an increase in urinary frequency. The biggest problem is extremely heavy menstrual bleeding. I bleed so fast that I suffer from light-headedness and become dizzy and nauseous to the point of almost passing out. I have always had nausea but it is now worse than before. The heavy bleeding and the severely painful menstrual periods tend to keep me down flat on my back for two or three days per month. Cannabis helps minimize monthly PMS symptoms. Cannabis helps relax my pelvic muscles, helps minimize pelvic pain, and helps release my muscle spasms and cramps, allowing me to function more easily physically.

46. *Recent Spinal Injury:* The effects of my scoliosis worsened several months ago after a very large man fell on my head, injuring my neck and back. The injury caused excruciating pain at the site of the injury, excruciating burning pain in my vertebrae, nerve problems going down both arms, and difficulties with my thumbs. The injury also caused some of my other pain conditions (TMJ, Rotator Cuff Syndrome, Headaches) to worsen. After a few months, the resulting pain caused me to experience multiple episodes of seizures and muscle spasms, which were also painful in their own right, further exacerbating my other chronic pain conditions and their related symptoms, and creating new and painful secondary injuries. Perhaps most critically, the injury caused my Fibromyalgia Syndrome worsen (see paragraph 38).

47. *My Medical Cannabis Use:* Before I became a medical cannabis patient I was against recreational marijuana use. In late 1997, my doctor felt cannabis would be an effective medication to treat my many complicated and complex medical conditions, and gave me my first recommendation to use medical cannabis. I eventually became a member of the Oakland Cannabis Buyers' Cooperative (OCBC) in early 1998, before the federal government filed suit against it. The OCBC was trying to provide me with medical grade cannabis. I was one of 14 "medical necessity" patients that the Oakland Cannabis Buyers' Cooperative was fighting for in the United States Supreme Court in 2001. The federal government, however, prevented the OCBC from giving me safe access to the one medication (medical cannabis) that keeps me alive. At that point I was forced to obtain my medication on the street. I was robbed, ripped off, and taken advantage of by the people selling the marijuana to me or to a friend on the street. Black market marijuana *is not* medical grade cannabis. One really does not know what is in that marijuana. It may contain mold, fungus, pesticides, other drugs, rat droppings, or god knows what. One does not know how it was grown or processed. It is just not safe.

48. To be safer and to save money, I tried to grow my own cannabis about five years ago. Even though I am good at growing most house plants, I found that I could not grow my own cannabis. Indoor cannabis *does not* grow like a weed, as some people think. The cannabis plants needed special care, and they needed more than I was able to give physically. I kept having insect problems and I did not have enough room or ventilation in my house. I could not grow enough medicine for my

medical needs. Thus, as a single mother, to buy cannabis, I had to make choices such as which bills to pay that month, and whether I would have enough food to eat after I fed my children.

49. I am now blessed to have two wonderful caregivers who grow all of my medicine and are willing to take a huge risk with their own liberty to help keep me alive. That is true compassion. I am sure we would all be facing mandatory sentences just because we are growing a plant that happens to keep me alive and allows me to be here for my children. I would not be alive if it were not for these two caregivers. My caregivers both work very hard to help me fight my diseases. My caregivers grow my medicine specifically for me. They do not charge me, nor do we trade anything. They grow my medicine and give it to me free of charge. They both grow different strains of cannabis for me to treat my medical conditions. One strain of medical cannabis helps my chronic pain, one helps my seizures, one helps me eat and hold onto my weight, and another may helps control my nausea. All of these different strains of medical cannabis are very beneficial and essential to my survival. Not all strains of cannabis work for me. Because the different strains have different growth cycles, one caregiver *could not* grow all of the medical cannabis I require to keep my weight up and my pain levels down. Moreover, I can not risk having all of my medicine in one place because I can not afford to lose my whole garden if there is a pest problem or if it were raided by federal agents. The caregivers who grow my medicine are my co-plaintiffs, known as in this litigation as JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO.

50. In the cultivation of my medical cannabis, JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO, of Oakland, California, use only soil, water, and nutrients originating from within the borders of the State of California. JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO also use only growing equipment, supplies, and lumber manufactured within the borders of the State of California. JOHN DOE NUMBER ONE and JOHN DOE NUMBER TWO cultivate for me medical-grade cannabis free of mold, fungus, pesticide residue, and other contaminates in the particular strains that I have found to be most effective in treating my specific medical conditions.

51. Both of my caregivers not only grow my medical-grade cannabis but they also process the cannabis into hashish or keif. Additionally, I process the cannabis into cannabis oil for cooking, I make cannabis therapeutic massage oil, I make cannabis therapeutic skin balm, and I make cannabis foods.

52. I provide the following information to my caregivers to try to keep them safe and protect my medicine in case law enforcement agents raid the garden areas:

A. Copies of my doctors' recommendations for the use of medical cannabis,

B. A copy of my Oakland Cannabis Buyers' Cooperative I.D. Card that states I am a "medical necessity" patient and confirms that my recommendation is valid,

C. Copies of some of my medical records, and

D. A signed caregiver statement that says my caregivers provide my medical cannabis to me.

In total, my caregivers grow over eight pounds per year of medical-grade cannabis for me.

53. *Amount of Cannabis I Use:* I use over two and one-half ounces of processed medical cannabis per week, or over eight pounds of cannabis per year. Cannabis does not get me "high." I cook and bake my own cannabis foods. I use my homemade cannabis oils to make massage oil and balm that I use to rub over my body, which helps my muscle spasms and cramps. I even used it on my stitches after surgery. It works like a miracle on rashes and hives. The worst side effect is the fear that at any moment the DEA could kick my door in and cause my and my family irreparable harm. My children, my husband, and myself are all aware of the risks we have been taking in order to keep me alive. We are willing to risk it all by telling about our family, and telling the Court all about my medical use of cannabis. Is the only effective way for me safely to treat all of my many medical conditions without becoming sicker. With cannabis I do not suffer from the side effects I experience with synthetic prescription medications. I am not a medical cannabis patient because I choose to be one—I am a medical cannabis patient because it is a necessity to keep me from dying. Taking a pill would be much easier and would take less time, but I simply do not have that option the way most others patient do. I have no other medical or legal alternative to sustain my life. Cannabis saved my life and gave my children their mother back. I would rather use cannabis to end the suffering from my conditions, and be alive, than to suffer endlessly knowing that there *is* something that could help treat my serious medical conditions. Cannabis is the only medication

that keeps me alive and makes my medical conditions more manageable and my life livable.

54. *How I Use Medical Cannabis:* I smoke or vaporize cannabis every two waking hours, and have every day since late 1997. Upon starting to use cannabis in 1997 I immediately noticed a huge difference in my medical conditions. I noticed an even bigger difference in 1998 when I started to ingest medical cannabis by eating cannabis brownies, cakes, candy, and milk. Using the smoked and vaporized cannabis and the ingested cannabis at the same time made the biggest improvement in my medical conditions. One of my problems is I am unable to sleep due to high levels of pain. If I am lucky enough to fall asleep, I may wake up in the middle of the night in tears. When I eat cannabis before bedtime it helps me sleep better. Rest is important for my healing process. Cannabis massage oil and balm used topically on my muscles and joints makes a big difference. Using all of these methods together seems to make the biggest impact on my health, and helps me to manage and cope better on a daily basis. It has made all the difference in the world. My doctors noticed, my children noticed, my friends noticed.

55. It is a miracle I am now walking, it is a miracle I am even alive. I still have functioning problems and extremely high levels of pain even with the cannabis, however cannabis controls the pain enough so I can walk again, and it keeps me from wasting away and starving to death. I am not willing to give up my life or go back into a wheelchair without a fight. Cannabis really does help my conditions. It keeps me alive and helps minimize my suffering. My cannabis use and doctors' recommendations are all documented in my medical records.

56. I know I am taking a huge risk by talking publicly about my medical cannabis use. I am in no way going to stop using cannabis. I am fighting to stay alive. I want to live! I am extremely afraid of being raided by federal agents. The fear I experience is having a negative effect on my medical conditions. If I am raided by federal agents or incarcerated and kept from using my medicine, I would be gravely ill in a short amount of time. My children need me to take care of them and help them grow up. I have never been arrested nor am I a threat to anyone. I am just a mother who is fighting to stay alive. I feel the United States Attorney General and the DEA Administrator Asa Hutchinson are waging a civil war against the sick, disabled, and dying Americans of our country. I am filing this lawsuit to fight for my constitutional right to life.

57. *My Media Attention:* Because of all the media coverage I have received, I am at greater risk of being raided by the federal government. After cannabis had freed me from my wheelchair I became more active in helping California medical cannabis patients. After the Supreme Court's 2001 decision in the Oakland Cannabis Buyers' Cooperative case, I received significant national and international media coverage. My photos and quotes were used in many newspapers across the United States, including the *New York Times* and *USA Today*. I spoke on national television saying I could not follow any federal law that purported to prevent me from using cannabis. Since then I have spoken at numerous events and conferences educating the public about the use of medical cannabis. I have taught classes on medical cannabis at high schools and colleges, and police academies.

58. *My Community Education and Community Service Activities:* I do my best to become involved in my community when my body allows me to participate. I am on the Oakland City Council's Medical Cannabis Task Force. I work with the Alameda County Public Health Department and the Alameda County Department of Children and Family Services regarding medical cannabis issues. I have spoken before city councils. I do not want other patients to suffer as I have to. We need to be taken off the battlefield of the "Drug War" right away. My life depends upon it. I feel I have been left with no choice: I have no alternative but to speak out. However, I fear that makes me an easy target based on numerous raids by federal agents against patients and growers. Outspoken patients have recently been targeted and raided by federal agents.

59. *How My Medical Conditions and My Use of Medical Cannabis Affected My Children:* My children have had a very difficult time adjusting to my many complex medical conditions. They know more than anyone how medical cannabis brought their mommy back to them. Before 1995, I was the neighborhood mother, who played basketball, roller bladed, played frequently with the children, managed my son's little league baseball team, and helped at the school. We would have all of the neighborhood children over to bake cookies, and we would do children's hobbies and crafts. We did all kinds of wonderful and fun things together. Our lives have never been the same since I became disabled, and never will be normal again. My medical conditions have affected my children emotionally. When I became disabled in September 1995, my daughter had just started kindergarten. She was so little that she just did not adjust well to my medical

conditions. At that young age my daughter would actually hit me when I was in my wheelchair. She was so angry because her mommy was gone, replaced by my diseases. My daughter was trying to beat the disease out of my body. My daughter was too little to understand what was happening to her mommy. She would lay on her bed and cry with sadness. I was unable to hold my daughter in my arms as I used to because the burning pain in my body would become worse if someone touched my skin, and my body was very debilitated. I really missed holding both of my children. I love them so much, I would do anything for them and I would do anything to keep them safe from harm. As the years passed my body continued to deteriorate, and I became weaker and weaker. The weaker I became from my diseases, the harder it was for my children.

60. One night I heard my daughter crying in bed. I went to her side and asked her why she was crying. She told me she was crying because I was disabled and sick. She wanted me to get out of my wheelchair. She wanted her mommy back. She asked me why, why can't I get better, why does her mommy have to be in a wheelchair. She cried for a long time. She often cried at night about my medical conditions. She missed me. It broke my heart. I told her to keep praying and maybe God would answer her prayers. I thought prayer was the best thing. She told me she had been praying and God did not hear her prayer. I told her to keep praying and ask Him to answer her and maybe her prayers would come true.

61. I do my very best to be there to support both of my children. My children and I have a great open communication. They know they can talk to me about

anything. I have to protect my children and do what is in their best interests.

62. Both of my children know that medical cannabis *is* legal under California State law. I asked my children if they wanted me to stop using my medicine because of the federal government. They both told me, "No Way." The expression on their little faces said it all. My children know that I am alive today because of medical cannabis. I do not want the DEA to raid my home and traumatize me or my family.

63. Medical cannabis has only medical benefits for me, I have not had one single negative experience from using cannabis medically. The most scary side effect is knowing that at any moment federal agents could kick my door in and hold me and my family prisoner. My children and my husband are all aware of the risks they have been taking in order to keep me alive. We are now willing to risk even more by disclosing my medical use of medical cannabis under oath herein.

64. *Conclusion:* For years I felt as if I was suffering in Hell. What I had to endure was unbelievable and indescribable torture. Somehow, I found a miracle sent down from heaven by an angel that brought me up from the pits of Hell, and saved my life. I was given medical cannabis! My life was saved by this new miraculous medicine and my life was forever changed. Healing had begun, and healing was my gift. I have seen the changes in my body, my doctors have seen the changes in my body, and my family and friends have seen my miracle. I am sorry, I can not stop using medical cannabis or I will die. I am not giving up the miracle I have been given to save my very life. I will not go back to Hell for anyone or anything. I implore the federal

government not to take my life from me. I want to live and grow in peace.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on this 25th day of October, 2002, in Oakland, California.

/s/ ANGEL MCCLARY RAICH
ANGEL MCCLARY RAICH

AUG 17 2004

No. 03-1454

In the Supreme Court of the United States

JOHN D. ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONERS

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate possession and manufacture of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use.

PARTIES TO THE PROCEEDING

Petitioners are John D. Ashcroft, Attorney General of the United States, and Karen P. Tandy, Administrator of the Drug Enforcement Administration.

Respondents are Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two.

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In the Supreme Court of the United States

No. 03-1454

JOHN D. ASHCROFT, ATTORNEY GENERAL, ET AL., PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-43a) is reported at 352 F.3d 1222. The order of the district court denying respondents' motion for a preliminary injunction (Pet. App. 44a-69a) is reported at 248 F. Supp. 2d 918.

JURISDICTION

The judgment of the court of appeals was entered on December 16, 2003. A petition for rehearing was denied on February 25, 2004 (Pet. App. 70a-71a). The petition for a writ of certiorari was filed on April 20, 2004, and was granted on June 28, 2004. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISIONS INVOLVED

The Commerce Clause of the United States Constitution, Article I, Section 8, Clause 3, provides:

> The Congress shall have Power * * * To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.

The Necessary and Proper Clause of the United States Constitution, Article I, Section 8, Clause 18, provides:

> The Congress shall have Power * * * To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

STATEMENT

1. a. The Controlled Substances Act (CSA or Act), 21 U.S.C. 801 *et seq.*, establishes a comprehensive federal scheme to regulate the market in controlled substances. The CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1). The CSA similarly makes it a crime to possess any controlled substance except as authorized by the Act. 21 U.S.C. 844(a). The CSA thus establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 6 (1970). To effectuate that closed system, the CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal." *United States* v. *Moore*, 423 U.S. 122, 141 (1975) (quoting H.R. Rep. No. 1444, *supra*, Pt. 1, at 3). Persons who violate the CSA are subject to criminal and civil penalties, and ongoing or anticipated violations may be enjoined. 21 U.S.C. 841-863, 882(a).

The restrictions that the CSA places on the manufacture, distribution, and possession of a controlled substance depend upon the schedule in which the drug has been placed. 21 U.S.C. 821-829. Since Congress enacted the CSA in 1970, marijuana and tetrahydrocannabinols have been classified as schedule I controlled substances. See Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 202, 84 Stat. 1249 (schedule I(c)(10) and (17)); 21 U.S.C. 812(c) (schedule I(c)(10) and (17)).[1]

A drug is listed in schedule I, the most restrictive schedule, if it has "has a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C). Under the CSA, it is unlawful to manufacture, distribute, dispense, or possess a schedule I drug, except as part of a strictly controlled research project that has been registered with the Drug Enforcement Administration (DEA) and approved by the Food and Drug Administration (FDA). 21 U.S.C. 841(a)(1), 823, 844(a); *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489-490, 492 (2001). By contrast, drugs listed in schedules II through V may be

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[1] Marijuana is defined under the CSA to include all parts of the cannabis plant and anything made therefrom, except for the mature stalks, fiber produced from the stalks, sterilized seeds, and oil from the seeds. 21 U.S.C. 802(16). Marijuana has been found to contain at least 483 separate chemicals, among which delta^9-tetrahydrocannabinol (delta^9-THC) is the primary psychoactive component. 66 Fed. Reg. 20,041 (2001).

dispensed and prescribed for medical use. Manufacturers, physicians, pharmacists and others who may lawfully produce, prescribe, or distribute drugs listed in schedules II through V must, however, comply with stringent statutory and regulatory provisions that control the manufacture and distribution of such drugs. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306; see pp. 32-33, 39-41, *infra*.

b. The CSA contains congressional findings and declarations regarding the effects of drug distribution and use on the public health and welfare and the effects of intrastate drug activity on interstate commerce. After stating that "[m]any of the drugs included within [the CSA] have a useful and legitimate medical purpose and are necessary to maintain the health and welfare of the American people," 21 U.S.C. 801(1), Congress found that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. 801(2). Congress then found:

> A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—
>
> (A) after manufacture, many controlled substances are transported in interstate commerce,
>
> (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

> (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

21 U.S.C. 801(3). Congress further found that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances," 21 U.S.C. 801(4); that "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate" and "[t]hus, it is not feasible to distinguish" between such substances "in terms of controls," 21 U.S.C. 801(5); and that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic," 21 U.S.C. 801(6).

2. On October 9, 2002, respondents filed suit in the United States District Court for the Northern District of California against John Ashcroft, the Attorney General of the United States, and Asa Hutchinson, then Administrator of the DEA, seeking injunctive and declaratory relief barring those officials from enforcing the CSA with respect to their conduct. The complaint alleges that respondents Angel McClary Raich and Diane Monson are California citizens who use marijuana for medical purposes based on the recommendations of their physicians. Such use is exempted from the coverage of California's criminal drug laws. Pet. App. 1a-2a, 45a; see California Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West Supp. 2004) (exempting from the State's criminal laws the possession or cultivation of marijuana for "personal medical purposes" by a patient or her primary caregiver, "upon the written or oral

recommendation or approval of a physician" that marijuana would assist in the treatment of "any * * * illness for which marijuana provides relief").

Raich, a resident of Oakland, California, alleges that she suffers from numerous severe and debilitating medical conditions for which marijuana alone provides relief, and that her physicians recommend that she "medicate" with marijuana every two hours. Pet. App. 5a; J.A. 24, 27. Raich alleges that she is unable to cultivate her own marijuana and that she obtains marijuana free of charge from two "caregivers," respondents John Doe Number One and John Doe Number Two, who are also residents of Oakland, California, and who sued anonymously to protect Raich's marijuana supply. Pet. App. 5a, 14a n.3; J.A. 25-26. Although the Does cultivate the marijuana, Raich processes some of the marijuana into cannabis oils, balm, and foods. Pet. App. 5a.

Diane Monson, a resident of Butte County, California, alleges that she suffers from severe chronic back pain and constant, painful muscle spasms, and that she has been using marijuana to treat her symptoms for more than five years. Pet. App. 5a; J.A. 24-25. In August 2002, federal agents, pursuant to a search warrant, entered Monson's residence and seized six marijuana plants. J.A. 24; see 21 U.S.C. 881(g).

Respondents' suit sought a preliminary injunction to bar the government from enforcing the Controlled Substances Act against them to the extent that it prevents Raich and Monson from possessing, cultivating, and processing marijuana for their purported medical use, and to the extent that it prevents the John Doe respondents from cultivating marijuana and distributing it to Raich for her purported medical use. J.A. 37-39. Respondents urged that the CSA, as applied to their conduct, is unconstitutional and conflicts with what they

characterized as a "doctrine of medical necessity." Pet. App. 6a.

On March 4, 2003, the district court denied the motion for a preliminary injunction, concluding that "the weight of precedent precludes a finding of likelihood of success on the merits." Pet. App. 45a.

3. A divided panel of the court of appeals reversed and remanded. Pet. App. 1a-43a.

a. The court of appeals concluded that respondents "have demonstrated a strong likelihood of success on their claim that, as applied to them, the CSA is an unconstitutional exercise of Congress' Commerce Clause authority." Pet. App. 9a. The court expressed the view that its previous decisions that had uniformly rejected Commerce Clause challenges to the CSA were not controlling, because none of those decisions "involved the use, possession, or cultivation of marijuana for medical purposes." *Id.* at 10a.

In the court's view, the "intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician" "constitutes a separate and distinct class of activities" that is beyond Congress's power to regulate under the Commerce Clause. Pet. App. 11a (emphasis omitted). The court found that class to be "different in kind from drug trafficking," stating that "this limited use is clearly distinct from the broader illicit drug market—as well as any broader commercial market for medicinal marijuana—insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." *Ibid.*

The court of appeals also reasoned that "[t]he cultivation, possession, and use of marijuana for medicinal purposes and not for exchange or distribution is not properly characterized as commercial or economic

activity." Pet. App. 14a. On that basis, the court found "not applicable" the "aggregation principle" of *Wickard* v. *Filburn*, 317 U.S. 111 (1942), which, in determining the constitutionality of an Act of Congress under the Commerce Clause, allows for consideration of the cumulative impact on interstate commerce of individual instances of regulated conduct (in *Wickard*, the production of wheat). Pet. App. 15a. The court also rejected the importance of Congress's findings in the CSA regarding the effects of intrastate drug activity on interstate commerce, stating that "[t]he findings are not specific to marijuana, much less intrastate medicinal use of marijuana that is not bought or sold and the use of which is based on the recommendation of a physician," and that in any event such findings should be taken "with a grain of salt." *Id.* at 19a-20a. Finally, the court concluded that the balance of hardships of the parties and public interest factors "tip sharply" in favor of the entry of a preliminary injunction barring enforcement of the CSA. *Id.* at 24a.

b. Judge Beam dissented. Pet. App. 26a-43a. In his view, "[i]t is simply impossible to distinguish the relevant conduct surrounding the cultivation and use of the marijuana crop at issue in this case from the cultivation and use of the wheat crop that affected interstate commerce in *Wickard* v. *Filburn*, [*supra*]." *Id.* at 26a. The dissent explained that the court of appeals' approach ignored "the fungible, economic nature of the substance at issue—marijuana plants—for which there is a well-established and variable interstate market, albeit an illegal one under federal law." *Id.* at 34a; accord *id.* at 34a-35a (Respondents "are growing and/or using a fungible crop which *could* be sold in the marketplace, and which is also being used for medicinal

purposes in place of other drugs which would have to be purchased in the marketplace.").

Judge Beam also concluded that Congress's power to regulate respondents' activities is essential to Congress's ability to regulate "the larger commercial activity" covered by the CSA. Pet. App. 36a. He thus reasoned that, "[i]f Congress cannot reach individual narcotics growers, possessors, and users, its overall statutory scheme will be totally undermined." *Id.* at 38a. Finally, Judge Beam criticized the court's decision to carve out from Congress's general regulatory scheme individual instances of activity based on their ostensibly *de minimis* relation to commerce. *Id.* at 35a-37a.

c. On February 25, 2004, the court of appeals denied the government's petition for rehearing and rehearing en banc. Pet. App. 70a-71a.

4. On May 14, 2004, the district court on remand entered a preliminary injunction enjoining the Attorney General and the Administrator of DEA "from arresting or prosecuting Plaintiffs Angel McClary Raich and Diane Monson, seizing their medical cannabis, forfeiting their property, or seeking civil or administrative sanctions against them with respect to the intrastate, non-commercial cultivation, possession, use, and obtaining without charge of cannabis for personal medical purposes on the advice of a physician and in accordance with state law, and which is not used for distribution, sale, or exchange." Preliminary Injunction Order 1-2 (2004), appeal docketed, No. 04-16296 (9th Cir. June 28, 2004).

SUMMARY OF ARGUMENT

A. Congress has the power under the Commerce Clause, Art. I, § 8, Cl. 3, and the Necessary and Proper Clause, Art. I, § 8, Cl. 18, to regulate local activity that

substantially affects interstate commerce. In *Wickard* v. *Filburn*, 317 U.S. 111 (1942), the Court held that Congress could regulate the production of wheat for consumption rather than sale because that activity affected the regulated interstate market of wheat. *Wickard* establishes that Congress may regulate local activity that is "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *United States* v. *Lopez*, 514 U.S. 549, 561 (1995). Congress's determination that local activity with respect to a product substantially affects interstate commerce or could interfere with Congress's objective in regulating the interstate market of that product is entitled to substantial deference. *E.g.*, *Hodel* v. *Indiana*, 452 U.S. 314, 323-324 (1981).

B. The CSA constitutionally regulates the commercial market in marijuana, which is international and interstate in scope. Marijuana is regularly imported into the United States illegally, and domestic trafficking in the drug occurs on a massive scale. Indeed, marijuana traffickers collected an estimated $10.5 billion from American users in 2000 alone. Office of Nat'l Drug Control Policy, Exec. Office of the President, *Marijuana Fact Sheet* 5 (Feb. 2004) (*Marijuana Fact Sheet*). Because marijuana trafficking is quintessentially commercial activity that occurs in interstate and foreign commerce and substantially affects interstate commerce, Congress has the power under the Commerce Clause to regulate all commercial marijuana activity, including commercial possession, manufacture, and distribution that occurs wholly intrastate. *Lopez*, 514 U.S. at 560 ("Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.").

C. The CSA also constitutionally applies to the intrastate manufacture and possession of controlled substances, including marijuana, for personal use, and to the distribution of those substances without charge. Congress has concluded that regulation of all intrastate drug activity "*is essential* to the effective control" of interstate drug trafficking. 21 U.S.C. 801(6) (emphasis added). Congress also has found that controlled substances are readily bought and sold in interstate commerce, 21 U.S.C. 801(3); that local drug possession and distribution swell the interstate drug market, 21 U.S.C. 801(4); and that controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances in the interstate market, 21 U.S.C. 801(5).

Congress accordingly concluded that regulation of intrastate drug activity was a reasonably necessary means to accomplish its comprehensive regulation of the interstate market in controlled substances. Federal regulation of simple drug possession limits the demand for and marketing of the drug. Federal regulation of drug activity that involves personal use or free distribution also permits Congress to control illicit trafficking, as law enforcement officials often cannot readily ascertain whether an unlabeled drug resulted from a sale or will be sold. And excepting drug activity for personal use or free distribution from the sweep of the CSA would discourage the consumption of lawful controlled substances and would undermine Congress's intent to regulate the drug market comprehensively to protect public health and safety. For these reasons, Congress constitutionally has regulated respondents' activities as "an essential part of a larger regulation of economic activity, in which the regulatory scheme could

be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561.

D. In holding that the CSA is unconstitutional in its application to respondents' possession and distribution of marijuana, the Ninth Circuit improperly characterized those activities as non-economic and distinct from the more general interstate market of marijuana regulated under the CSA. Respondents' conduct is economic activity that is subject to congressional control because it occurs in, and substantially affects, the marijuana market generally. Home-grown marijuana displaces drugs sold in both the open drug market and the black drug market regulated by the CSA. Respondents' possession and distribution of marijuana also significantly interfere with Congress's objectives in comprehensively regulating the interstate drug market.

The court of appeals also erred in relying on the asserted "medical" nature of respondents' activities. Congress has the power to regulate the interstate market in marijuana as well as activity that substantially affects that market, regardless of the purported use of the drug. Indeed, much of the CSA is addressed to the regulation of substances that (unlike marijuana) have been found by the Secretary of Health and Human Services and the Attorney General to have an accepted medical use. Moreover, the court of appeals relied on policy judgments about the utility and safety of marijuana use that Congress has categorically rejected in the CSA.

ARGUMENT

THE CONTROLLED SUBSTANCES ACT CONSTITUTIONALLY APPLIES TO ALL MANUFACTURE, DISTRIBUTION, AND POSSESSION OF MARIJUANA

It is clear that Congress has the authority under the Commerce Clause to regulate the manufacture, distribution, and possession of marijuana, including when such acts are done in furtherance of purported personal medical use. Congress unquestionably has the power under the Commerce Clause to enact a comprehensive drug statute to regulate and control both interstate and intrastate trafficking in controlled substances, a class of activities that includes commercial manufacture, distribution, and resulting possession of controlled substances.- Congress does not lose its authority if the distribution and possession are not only intrastate, but also allegedly involve marijuana that is home-grown or distributed for free for personal use. Nor does Congress's authority turn on whether the personal use is "medicinal," rather than recreational. Intrastate activities involving marijuana for personal use substantially affect the drug market regulated under the CSA, and exempting such activities would significantly undercut the effectiveness of the comprehensive regulatory regime Congress established to control drug trafficking and abuse. Nor is the purported use of a drug relevant for purposes of determining Congress's power under the Commerce Clause. Indeed, respondents' purported medicinal use of marijuana, a schedule I drug, directly interferes with Congress' comprehensive regulation of the drug and squarely conflicts with Congress's determination that the drug has no accepted medicinal use.

A. Congress May Constitutionally Regulate Activity That Occurs In Or That In The Aggregate Substantially Affects A Regulated Interstate Commercial Market

1. Congress has the power "[t]o regulate Commerce with foreign Nations, and among the several States," Art. I, § 8, Cl. 3, and Congress has corresponding authority under the Necessary and Proper Clause, Art. I, § 8, Cl. 18, to pass legislation that constitutes a reasonable means to effectuate the regulation of interstate commerce. "Congress' commerce authority includes the power to regulate those activities having a substantial relation to interstate commerce, . . . *i.e.*, those activities that substantially affect interstate commerce." *United States* v. *Morrison*, 529 U.S. 598, 609 (2000) (quoting *United States* v. *Lopez*, 514 U.S. 549, 558 (1995)). Thus, it has long been established that "[t]he power of Congress over interstate commerce is not confined to the regulation of commerce among the states. It extends to those activities intrastate which so affect interstate commerce or the exercise of the power of Congress over it as to make regulation of them appropriate means to the attainment of a legitimate end, the exercise of the granted power of Congress to regulate interstate commerce." *United States* v. *Darby*, 312 U.S. 100, 118 (1941); accord *Wickard*, 317 U.S. at 124 (quoting *United States* v. *Wrightwood Dairy Co.*, 315 U.S. 110, 119 (1942)); see *NLRB* v. *Jones & Laughlin Steel Corp.*, 301 U.S. 1, 36-37 (1937) ("[T]he power to regulate commerce is the power to enact 'all appropriate legislation' for 'its protection and advancement.'") (citing *The Daniel Ball*, 77 U.S. (10 Wall.) 557, 564 (1870)).

This Court's precedents also confirm that "where *a general regulatory statute bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under that statute is of no consequence." *Lopez*, 514 U.S. at 558 (quoting *Maryland* v. *Wirtz*, 392 U.S. 183, 197 n.27 (1968)); accord *Perez* v. *United States*, 402 U.S. 146, 154 (1971) ("Where the *class of activities* is regulated and that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class.") (quoting *Wirtz*, 392 U.S. at 193).

That principle is illustrated by *Wickard* v. *Filburn*, *supra*, in which the Court upheld the federal regulation of wheat, which was grown and consumed on a family farm, as part of a comprehensive program to control the volume and price of wheat moving in interstate and foreign commerce. The Court reached that result even though the wheat was not "sold or intended to be sold," 317 U.S. at 119; the production of wheat "may not be regarded as commerce," *id.* at 125, and the regulated individual's own activity "may be trivial by itself," *id.* at 127. The Court explained that local activity may, "whatever its nature, be regulated by Congress if it exerts a substantial effect on interstate commerce." *Id.* at 125. In *Wickard* itself, the Court held that Congress's regulation of the purely local activity of growing wheat even for consumption on the farm was reasonably necessary to achieve Congress's broader regulation of the supply, demand, and prices in the interstate wheat market, which is indisputably subject to its power under the Commerce Clause. *Id.* at 127-129.

Wickard thus establishes that Congress may regulate intrastate activity which itself may not be overtly commercial in nature—in the sense that it does not directly involve an exchange for valuable consideration—if regulation of the activity is reasonably neces-

sary to achieve the effective regulation of a market that is interstate in nature. This Court explained in *Lopez*, *supra*, that the production of wheat that Congress chose to regulate in *Wickard* was subject to federal regulation even though the specific wheat at issue was produced for personal use and the regulated activity "may not be regarded as commerce." *Lopez*, 514 U.S. at 556 (quoting *Wickard*, 317 U.S. at 125). In distinguishing the statute in *Wickard* from the Gun-Free School Zones Act of 1990, 18 U.S.C. 922(q), at issue in *Lopez*, the Court explained that "*Wickard* * * * involved economic activity in a way that the possession of a gun in a school zone does not." *Lopez*, 514 U.S. at 560. The Court further explained that, unlike the statute in *Wickard*, Section 922(q) was not "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561; see also *Morrison*, 529 U.S. at 610.

2. In determining whether a federal statute may be sustained as a proper exercise of Congress's power to regulate interstate commerce, courts apply a "rational basis" standard that reflects broad deference to legislative judgments regarding whether the intrastate activity at issue substantially affects interstate commerce and whether regulation of the activity is reasonably necessary to achieve Congress's purposes. See *Lopez*, 514 U.S. at 557; *Wirtz*, 392 U.S. at 198. "A court may invalidate legislation enacted under the Commerce Clause only if it is clear that there is no rational basis for a congressional finding that the regulated activity affects interstate commerce, or that there is no reasonable connection between the regulatory means selected and the asserted ends." *Hodel* v. *Indiana*, 452 U.S. at 323-324; see *e.g.*, *Jinks* v. *Richland County*, 538

U.S. 456, 461-464 (2003); *Preseault* v. *ICC*, 494 U.S. 1, 17 (1990); *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316, 419 (1819); accord *Sabri* v. *United States*, 124 S. Ct. 1941, 1946 (2004) (Spending Clause).

B. The CSA Comprehensively Regulates The Market In Controlled Substances

1. Congress passed the CSA "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States * * * through providing more effective means for law enforcement aspects of drug abuse prevention and control." H.R. Rep. No. 1444, *supra*, Pt. 1, at 1; accord S. Rep. No. 613, 91st Cong., 1st Sess. 3 (1969) ("[T]he overall purpose of the bill is to improve the administration and regulation of the manufacture, importation and exportation of the controlled dangerous substances covered under its provisions, so that the widespread diversion presently occurring can be halted."). In furtherance of its central purposes, the CSA comprehensively bans *all* manufacture, distribution, and possession of any scheduled drug unless explicitly authorized by the Act. 21 U.S.C. 841(a)(1), 844(a). That is why marijuana, like all other listed drugs, is a "controlled" substance under the CSA. The Act thus establishes "a 'closed' system of drug distribution" for all controlled substances by "provid[ing] for control * * * of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and [by] mak[ing] transactions outside the legitimate distribution chain illegal." H.R. Rep. No. 1444, *supra*, Pt. 1, at 3, 6. Congress thereby sought to "significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug

industry with a unified approach to narcotic and dangerous drug control." *Id.* at 6; see *Moore*, 423 U.S. at 135, 141.

2. The CSA obviously includes within its comprehensive scope quintessentially commercial activity—the manufacture and distribution of drugs for consideration, and the possession of drugs in connection with or as a result of such transactions—that in large part takes place *in* interstate and foreign commerce and that categorically *affects* interstate commerce. Congress in the CSA found that "[a] major portion of the traffic in controlled substances flows through interstate and foreign commerce." 21 U.S.C. 801(3). Congress was also aware that the national drug abuse problem sought to be addressed by the CSA stemmed from "the illicit traffic in drugs which is both international and interstate in scope." S. Rep. No. 613, *supra*, at 3. Congress accordingly determined that "Federal * * * regulation and control [of controlled substances] is required to help manage the drug abuse problem and the criminal traffic in drugs on the international, national, and State levels." *Id.* at 4.

Those judgments were well founded and remain accurate today. "The illegal drug market in the United States is one of the most profitable in the world." DEA, *Drug Trafficking in the United States* 1 (Sept. 2001) (*Drug Trafficking*) <http://www.usdoj.gov/dea/concern/drug_trafficking.html>. A diverse and sophisticated group of international and domestic traffickers engage in the illicit commercial manufacture, distribution, and possession of drugs in this country. For instance, "[c]riminal groups operating from South America smuggle cocaine and heroin into the United States"; "criminal groups operating from neighboring Mexico smuggle cocaine, heroin, methamphetamine, amphetamine, and marijuana into the United States"; and "Israeli and Russian drug trafficking syndicates and Western Europe-based drug traffickers are the principal traffickers of MDMA [ecstasy] worldwide." *Ibid.*; accord S. Rep. No. 613, *supra*, at 3-4 ("There is an unknown quantity of the nonmedical and nonprescription drugs (heroin, cocaine, marihuana) being continuously smuggled into this country."). In addition to the criminal groups based abroad, "domestic organizations cultivate, produce, manufacture, or distribute illegal drugs such as marijuana, methamphetamine, phencylidine (PCP), and lysergic acid diethyamide(LSD)." *Drug Trafficking* 1.

The interstate market for marijuana that Congress regulates under the CSA is well-established and substantial. At the time Congress passed the CSA, marijuana was "the most popular drug of abuse," and marijuana offenses had accounted for "the bulk of drug arrests throughout the Nation." S. Rep. No. 613, *supra*, at 2, 3. Even today, despite the federal prohibitions on marijuana, "[t]he indoor and outdoor cultivation in most regions of the country, as well as the presence of marijuana smuggled into the United States from foreign sources, contributes to the pervasiveness of the drug." Drug Availability Steering Committee, *Drug Availability in the United States* 103 (Dec. 2002) (*Drug Availability*) <http://www.whitehousedrugpolicy.gov/publications/pdf/drugavailability.pdf>. Indeed, "U.S. marijuana users spent approximately $10.5 billion on marijuana in 2000." *Marijuana Fact Sheet* 5. The illicit marijuana market is also well-defined according to geographic areas and the particular type of marijuana being sold. National Drug Intelligence Center, *National Drug Threat Assessment 2004*, at 3 (Apr. 2004) (*National Drug Threat Assessment*) ("Marijuana

prices, an indication of marijuana's steady availability, have been stable for years, although prices range considerably from market to market depending on the type and potency available, quantity purchased, purchase frequency, buyer-seller relationship, and proximity to source.") <http://www.usdoj.gov/ndic/pubs8/8731/marijuana.htm>; *Illicit Drug Prices July 2003-December 2003*, Narcotics Digest Weekly, Dec. 16, 2003, at 1 & Table 4, at 19-25 (listing, for all 50 States and District of Columbia, wholesale, midlevel, and retail prices for "BC Bud" (*i.e.*, high-potency Canadian), commercial grade, domestic, hydroponic, locally produced, imported, Mexico-produced, and sinsemilla marijuana). And marijuana is readily and commonly transported across state lines. *E.g.*, *National Drug Threat Assessment* 13-14 ("Throughout the United States a wide range of organizations, groups, gangs, and independent dealers transport—and distribute—marijuana."). Congress's commerce power accordingly extends to the comprehensive regulation of all commercial marijuana activity throughout the Nation.

C. The CSA Constitutionally Includes Wholly Intrastate Manufacture, Free Distribution, And Possession Of Marijuana

Respondents' intrastate drug distribution and use are subject to congressional regulation because Congress rationally determined that such activities as a class substantially affect the marijuana market as a whole. Regulation of such activities also is a necessary and proper means to effectuate Congress's comprehensive regulation of the interstate market for marijuana. Indeed, the CSA is a compelling instance in which Congress's power "extends to those activities intrastate which so affect interstate commerce or the

exercise of the power of Congress over it as to make regulation of them appropriate means to the attainment of a legitimate end." *Darby*, 312 U.S. at 118.

Congress manifestly has the authority under the Commerce Clause to regulate the *commercial* manufacture, distribution, and possession of any controlled substance, even if such activity takes place entirely *intrastate*. *Lopez*, 514 U.S. at 559 ("[W]e have upheld a wide variety of congressional Acts regulating intrastate economic activity where we have concluded that the activity substantially affected interstate commerce."); see *e.g.*, *United States* v. *Wrightwood Dairy Co.*, 315 U.S. 110, 118-121 (1942); *Darby*, 312 U.S. at 118-119. This Court's decisions thus firmly establish that Congress may ban a commercial activity, whether it occurs in interstate or intrastate commerce, when the commercial activity, in the aggregate, affects interstate commerce. See, *e.g.*, *Perez*, *supra* (loan sharking); *Minor* v. *United States*, 396 U.S. 87, 98 (1969) (observing that "a flat ban on certain sales [of narcotics] is sustainable under the powers granted Congress in Art. I, § 8.").

Likewise, the fact that respondents' conduct is not only intrastate, but also purportedly limited to distribution and possession for personal use, does not eliminate Congress's authority. The constitutionality of the CSA as applied to drug distribution and possession for personal use follows from the Court's unanimous decision in *Wickard*, and from the Court's reaffirmation of *Wickard* in *Lopez*. See *Brzonkala* v. *Virginia Polytechnic Inst. & State Univ.*, 169 F.3d 820, 836 n.7 (4th Cir. 1999) (en banc), aff'd *sub nom. United States* v. *Morrison*, 529 U.S. 598 (2000). The growing and processing of marijuana and its resulting possession for personal use "involve[] economic activity"—the production of a fungible commodity for which there is an

established market—in the same way as the growing of wheat for consumption does, and "in a way that possession of a gun in school zone does not." *Lopez*, 514 U.S. at 560. Judge Luttig made that very point in distinguishing the regulation of marijuana for personal use under the CSA from the provision of the Violence Against Women Act struck down in *Morrison*, *supra*, observing that, "[l]ike the production of home-grown wheat, the manufacture of marijuana for personal use is an economic activity in a general sense." *Brzonkala*, 169 F.3d at 836 n.7. As Judge Luttig further explained, in both situations, the activity is regulated "pursuant to a comprehensive statutory scheme" regulating the trade of a product "which is assuredly both commercial and interstate." *Ibid.* "Thus, like the regulation of home-grown wheat, the prohibition of home-grown marijuana is 'an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated.'" *Ibid.* (quoting *Lopez*, 514 U.S. at 561); accord *United States* v. *Lopez*, 2 F.3d 1342, 1367 n.51 (5th Cir. 1993) ("The [CSA's] possession proscription [is] a necessary means to regulate the interstate commercial trafficking in narcotics."), aff'd, 514 U.S. 549 (1995). As explained below, those conclusions are amply supported by Congress's findings when it enacted the CSA and the nature of the problem that the CSA addresses.

1. Congress reasonably found that intrastate drug manufacture, distribution, and possession substantially affect interstate drug commerce and that federal regulation of that intrastate activity is essential to achieve Congress's regulation of drug commerce

a. Section 801 of the CSA sets forth "the principal reasons" why Congress deemed it "necessary to make

the controls of [the CSA] applicable to all controlled substances regardless of whether they or their components have ever been outside the State in which they are found." H.R. Rep. No. 1444, *supra*, Pt. 1, at 29. Congress concluded that, although the manufacture, local distribution, and possession of controlled substances "are not an integral part of the interstate or foreign flow" of drugs, those activities are nonetheless "incidents" of the interstate and foreign drug traffic that "have a substantial and direct effect upon interstate commerce." 21 U.S.C. 801(3). Significantly, Congress did *not* rely on the aggregate effects of illicit local drug activity on the *national economy*. See *Morrison*, 529 U.S. at 615-619. Rather, Congress viewed intrastate drug activity as significantly affecting the interstate *market* for the drugs that are regulated under the statute. Specifically, Congress found that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances" (21 U.S.C. 801(4)); that "after manufacture, many controlled substances are transported in interstate commerce" (21 U.S.C. 801(3)(A)); that "controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution," (21 U.S.C. 801(3)(B)); and that "controlled substances possessed commonly flow through interstate commerce immediately prior to such possession," 21 U.S.C. 801(3)(C); accord H.R. Rep. No. 1444, *supra*, Pt. 1, at 29. For those reasons, Congress concluded that "*[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.*" 21 U.S.C. 801(6) (emphasis added).

Those findings fully support Congress's conclusions that the local manufacture, distribution, and possession

of drugs, including marijuana, are significantly linked to the commerce in drugs regulated under the statute and that comprehensive regulation of that local activity is essential to effectuate control of the interstate drug market.[2] Local manufacture, distribution, and use of controlled substances—and their possession for those purposes—directly increase the supply of those substances, which in turn increases demand for these substances, which leads to further increases in supply and the marketing to users, thus "swelling" the traffic in the drug. 21 U.S.C. 801(4). "Laws criminalizing the possession of a good decrease the demand for that good. This decreased demand results in a decrease of supply as production becomes less profitable and therefore less attractive." *United States* v. *Adams*, 343 F.3d 1024, 1033 (9th Cir. 2003), cert. denied, 124 S. Ct. 2871 (2004). A criminal ban on possession also serves as "a marketing impediment to those inclined to violate the prohibition on sale." *United States* v. *Franklyn*, 157 F.3d 90, 96 (2d Cir. 1998), cert. denied, 525 U.S. 1112 (1999); cf. *Osborne* v. *Ohio*, 495 U.S. 103, 109-110 (1990) ("It is

[2] The Ninth Circuit concluded that the Court's decision in "*Morrison* counsels courts to take congressional findings with a grain of salt." Pet. App. 20a. That is not correct. *Morrison* held that Congress lacked the power under the Commerce Clause to regulate gender-motivated violence despite Congress's findings that such violence had significant effects on the national economy and interstate commerce. 529 U.S. at 615-619. The Court did not, however, cast doubt on its earlier decisions holding that Congress's findings are entitled to deference. Rather, the Court assumed the rationality of Congress's findings, but concluded, as matter of constitutional principle, that Congress's justification was too broad because it would permit Congress to regulate all non-economic crimes in areas of traditional state regulation, thereby blurring the "distinction between what is truly national and what is truly local." *Id.* at 617-618.

* * * surely reasonable for the State to conclude that it will decrease the production of child pornography if it penalizes those who possess and view the product, thereby decreasing demand.").

If Congress lacked the power to regulate either the intrastate production, distribution, and possession of marijuana generally, or the production, distribution, and possession of marijuana for personal use, the market effects on the demand and supply of marijuana would likely be enormous. "[B]oth law enforcement and public health agencies consistently identify marijuana as the most commonly used illicit drug in the country." *National Drug Threat Assessment* 1. "The demand for marijuana far exceeds that for any other illicit drug and the size of the American user population equates to steady profits for traffickers." *Drug Availability* 103. The risk that both the supply and demand could dramatically increase were home-grown marijuana beyond the reach of federal law is obvious. Users of home-grown marijuana and those who distribute it for free (such as the John Doe respondents) may ultimately purchase marijuana in the black market, if, for example, their production efforts fail or fall short. Indeed, respondents, like many other claimed medical marijuana users, view marijuana consumption as a *medical necessity*. Br. in Opp. 26-29; Pet. App. 84a-85a; J.A. 32-33 (Complaint); *Oakland Cannabis*, *supra*.

The "home-grown" manufacturing, free distribution, and possession of controlled substances, whether for recreational or purported medicinal purposes, also pose an appreciable risk of diversion to others for further drug use or distribution, a result that further swells the illicit market. Local users may ultimately sell or divert the drug to others (for instance, should their production yield exceed their purported needs or should additional

funds be required to finance their drug production or other activities). The risk of diversion is particularly acute under the regime contemplated by the Ninth Circuit, in which persons, such as the John Doe respondents, may manufacture and distribute marijuana to others without charge. Such persons would have an available supply of home-grown marijuana to sell to meet their own financial needs, and they are likely to have no ready means to ensure that the recipients of the marijuana to whom they distribute it for free will not in turn put the drug into the stream of commerce. See Pet. App. 34a (Beam, J., dissenting) (Respondents "are growing and/ or using a fungible crop which *could* be sold in the marketplace.").

Finally, the fact that the purported personal use is for medical, rather than recreational, use does nothing to strengthen respondents' Commerce Clause challenge. In the first place, the entirety of the CSA involves the regulation of drugs, most of which, *i.e.*, those in schedules II through V, have some accepted medical use. See pp. 39-41, *infra*. In addition, local illicit drug use for purported medicinal purposes significantly affects the drug commerce subject to Congress's regulation by inducing the "medicinal" user to refrain from consuming lawful drugs, Pet. App. 34a-35a, 36a (Beam, J., dissenting), or by decreasing the incentives for research and development into new legitimate drugs. Cf. *United States* v. *Rutherford*, 442 U.S. 544, 556 (1979) ("[I]f an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible."). For instance, one method of delivery of cannabinoids currently available is Marinol®, which contains a synthetic form of tetrahdyrocannabinol (THC) in pill form. Marinol® has

been approved by the FDA for the treatment of nausea and vomiting associated with cancer chemotherapy and for the treatment of anorexia associated with weight loss in AIDS patients. 64 Fed. Reg. 35,928 (1999). On July 2, 1999, DEA transferred Marinol® from schedule II to schedule III under the CSA, thereby lessening the regulatory restrictions on its use. *Id.* at 35,929. Indeed, respondents Raich and Monson were users of many lawful prescription drugs that are controlled under the CSA, including Marinol®, before they turned to marijuana. J.A. 49-50, 53, 56. Although particular individuals such as respondents may find that lawful drugs such as Marinol® are ineffective or cause serious side-effects, Congress rationlly and constitutionally concluded that the public should use only those drugs that the FDA has approved as safe and effective for some medical use—and, if listed under the CSA because of their potential for abuse and dependency, subject to the CSA's stringent controls that guard against abuse and diversion.

For the foregoing reasons, Congress's unquestionable power to eradicate drug trafficking and distribution also includes the power to ban all production, possession, and use that feeds the illicit drug market. Indeed, courts have generally upheld laws that ban the intrastate possession or manufacture of a commodity as a reasonably necessary means of regulating commerce in the commodity. See, *e.g.*, *United States* v. *Rybar*, 103 F.3d 273, 283 (3d Cir. 1996) (federal statute validly "targets the possession of machine guns as a demand-side measure to lessen the stimulus that prospective acquisition would have on the commerce in machine guns"), cert. denied, 522 U.S. 807 (1997); *Navegar, Inc.* v. *United States*, 192 F.3d 1050, 1058 (D.C. Cir. 1999) (statutory ban on possession of assault weapons "is a

measure intended to reduce the demand"), cert. denied, 531 U.S. 816 (2000); *United States* v. *Cardoza*, 129 F.3d 6, 12 (1st Cir. 1997) ("[G]iven Congress' express purpose [to stop commerce in handguns by juveniles], its decision to punish both the supply (sale or transfer) and demand (possession) sides of the market is a means reasonably calculated to achieve its end. * * * * * The two prohibitions go hand in hand with one another. Invalidation of one half of the equation would likely have deleterious effects on the efficacy of the legislation.").[3]

b. This Court's cases also recognize that effective national approaches may require the regulation of purely local activity to prevent the circumvention of federal rules and to facilitate a comprehensive system of regulation. See, *e.g.*, *Wickard*, *supra*. In the CSA, Congress rationally addressed all activity involving controlled substances in light of the substantial difficul-

[3] Congress has passed many laws banning the intrastate possession of a product in order to eliminate an entire market for the commodity. *E.g.*, 16 U.S.C. 668(a) (bald and golden eagles); 18 U.S.C. 175(a) (biological weapons), 18 U.S.C. 831(a) (nuclear material), 18 U.S.C. 842(n)(1) (certain plastic explosives); 18 U.S.C. 922(o)(1) (machinegun); 18 U.S.C. 922(v)(1) (semiautomatic assault weapons); 18 U.S.C. 922(x)(1) (handguns by juveniles); 18 U.S.C. 2342(a) (contraband cigarettes); 18 U.S.C. 2252(a)(4)(B) (child pornography produced with materials shipped in interstate commerce); cf. *United States* v. *Bass*, 404 U.S. 336, 339 n.4 (1971) (declining to reach the question "whether, upon appropriate findings, Congress can constitutionally ban the 'mere possession' of firearms"). Shortly before its decision in this case, the Ninth Circuit issued two other decisions holding that Congress lacked power under the Commerce Clause to regulate possession of such products. *United States* v. *Stewart*, 348 F.3d 1132, 1134-1140 (2003) (homemade machinegun); *United States* v. *McCoy*, 323 F.3d 1114, 1117-1130 (2003) (home-produced child pornography).

ties that would be encountered by law enforcement officials if proof were required as to the origin of a drug or the commercial intentions of the person in whose possession the drug was discovered. As Congress found, many drugs produced are thereafter sold (21 U.S.C. 801(3)(A)), and many drugs possessed are the result of a previous sale (21 U.S.C. 801(3)(C)). Congress also found, however, that, given the fungible nature of drugs, "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate," and thus that "it is not feasible to distinguish" between such substances "in terms of controls." 21 U.S.C. 801(5); accord S. Rep. No. 613, *supra*, at 4.[4]

That finding comports with common sense, and fully justifies the regulation of intrastate as well as interstate activities. See, *e.g.*, *Darby*, 312 U.S. at 117-118; *Currin* v. *Wallace*, 306 U.S. 1, 11 (1939); compare *Sabri*, 124 S. Ct. at 1946. It often would be impossible to ascertain in any given case whether an illicit, unlabeled drug, such as marijuana, has either been purchased or

[4] Likewise, shortly before the passage of the CSA, Congress passed the Drug Abuse Control Amendments of 1965, which amended the Food, Drug and Cosmetic Act, to establish controls for depressant and stimulant drugs. Pub. L. No. 89-74, 79 Stat. 226. Congress therein found that "in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible." § 2, 79 Stat. 227. In enacting the CSA, Congress reasonably drew upon its earlier experience in attempting to control the interstate drug market. See *Fullilove* v. *Klutznick*, 448 U.S. 448, 503 (1980) (Powell, J., concurring).

is intended to be offered for sale. That is true not only of the processed marijuana smoked by respondents Raich and Monson, but also of the other home-made marijuana products such as "cannabis oils, balm, and foods" that Raich processes and consumes. Pet. App. 5a. There accordingly would be difficult, if not impossible, questions of proof if the government were required to demonstrate that a given quantity of marijuana that a person possessed, manufactured, or distributed to others without charge had previously entered, or would enter, into the stream of monetary commerce. Indeed, much of the marijuana obtained by users "for free" from friends or acquaintances was, at some earlier point, presumably purchased in a commercial transaction. Cf. *Marijuana Fact Sheet* 4 ("About 79% of marijuana users who bought the drug and 81.8% who obtained the drug for free got it from a friend."). But *proof* of that prior commercial chain of custody would be exceedingly difficult. Those difficulties of proof would be compounded by the fact that commercial production, distribution, and related possession of marijuana take place in an *illicit* market. The illicit nature of the market requires that the activity be undertaken in a clandestine manner to evade detection by law enforcement officers, see, *e.g.*, *Drug Trafficking* 10, *National Drug Threat Assessment* 8-12, and is wholly inconsistent with the kind of regulation and labeling that would be required to prove (or disprove) that certain drugs flowed in interstate or foreign commerce or were not for medicinal use.

Moreover, because the FDA has never approved marijuana as safe and effective for any medicinal use, and Congress has determined in the CSA that marijuana has no acceptable medical uses, 21 U.S.C. 812(b)(1)(B), there are no federal standards by which to

judge how much marijuana appropriately could be possessed, home-grown, or distributed for personal "medicinal" use. Not surprisingly, marijuana users consume the drug "at varying rates and in unlike quantities," and the drug itself has widely "varying potency." *Drug Availability* 138. Thus, it would often be difficult to prove whether relatively small quantities of marijuana were being held, produced, or distributed for commercial, recreational or medicinal use. *E.g.*, *People* v. *Mower*, 49 P.3d 1067, 1072, 1084 (Cal. 2002) (holding that a jury question existed whether possession of 31 marijuana plants was for personal medicinal use under Cal. Health & Safety Code § 11362.5, where defense presented evidence that plants would yield harvest of five pounds and prosecution presented evidence that plants would yield between 31 and 62 pounds).

The Ninth Circuit dismissed these law enforcement concerns, observing that "the marijuana in the instant case never entered into and was never intended for interstate or foreign commerce." Pet. App. 21a n.7. The court, however, failed to explain how, under the court's decision, federal law enforcement officials would enforce the CSA as to persons consuming, possessing, growing, or distributing marijuana where specific proof of a commercial transaction or purpose is lacking. In those situations, the CSA could not be enforced even though Congress specifically found that controlled substances typically have or will enter the stream of commerce. 21 U.S.C. 801(3). Thus, Congress would lack the power to provide for the effective enforcement of the CSA with respect to a large category of individuals who are engaging in commercial activity clearly subject to congressional regulation. Given that there are an estimated 25.8 million current users of marijuana in the United States—even though the manufacture, distribu-

tion, and possession of marijuana are categorically *illegal* under federal law, *Marijuana Fact Sheet* 1—the law enforcement problems created by exempting non-commercial and intrastate marijuana activities from the CSA's reach could well be staggering.

A ban on all possession is accordingly essential to permit "law enforcement to effectively regulate the manufacture and transfers where the product comes to rest, in the possession of the receiver." *Navegar, Inc.*, 192 F.3d at 1059. As the Fifth Circuit has observed in rejecting a challenge to the statutory prohibition of possession of child pornography, a market "is pushed by supply and demand, whether manifested in swaps or purchase and sale," and "where the product is fungible, such that it is difficult if not impossible to trace, Congress can prohibit local possession in an effort to regulate product supply and demand and thereby halt interstate trade." *United States* v. *Kallestad*, 236 F.3d 225, 231 (2000).

2. Federally unregulated local manufacture, distribution, and possession of controlled substances would substantially undercut Congress's closed system of distribution of those dangerous drugs

The intrastate manufacture, possession, and free distribution of controlled substances would significantly interfere with Congress's objectives under the CSA to establish a national, comprehensive, uniform—and closed—statutory scheme to control the market in controlled substances in order to prevent the abuse and diversion of those substances. As discussed above (at 23-32), the unregulated intrastate manufacturing, possession, and distribution of a drug would contribute to the illicit trafficking in and marketing of the drug, would increase the likelihood that the drug would be

diverted and sold for illegitimate uses, and would prevent effective enforcement of the interstate ban on drug trafficking. The CSA's closed system of distribution was designed to address those serious problems, while at the same time providing a means for the production and distribution under the strict controls in the CSA itself of those controlled substances that (unlike marijuana) have been found to have accepted and legitimate medical uses.

The adverse effect of the court of appeals' decision on the administration and enforcement of the CSA is readily illustrated as applied to the manufacture, distribution, and possession of drugs listed in schedules II through V (such as methadone, codeine and other opioids), which may be dispensed and prescribed for medical use. 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B). Although such drugs have an accepted medical use in treatment, they nonetheless are subject to abuse and resulting dependence, with attendant adverse consequences to public health and safety. 21 U.S.C. 812(b)(2)(A) and (C), (3)(A) and (C), (4)(A) and (C), and (5)(A) and (C). The CSA accordingly requires manufacturers, physicians, pharmacies, and other legitimate handlers of such drugs to comply with stringent statutory and regulatory provisions that mandate registration with the DEA, require compliance with specific production quotas, establish security controls to guard against the theft or diversion of drugs, impose record-keeping and reporting obligations, and permit the drug to be distributed and dispensed only pursuant to specific order-form and prescription requirements. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306.

Were Congress to lack the power under the Commerce Clause to apply the CSA to the intrastate manufacture, free distribution, and possession of controlled

substances on schedules II through V, persons operating intrastate could function essentially as unregulated and unsupervised drug manufacturers and pharmacies without being subject to *any* of the federal controls Congress put in place under the CSA. That state of affairs would manifestly undermine the CSA's purposes to establish a comprehensive and unified approach to "dangerous drug control" and to guard against the risks of drug abuse and the diversion of controlled substances from "legitimate channels into the illicit market." H.R. Rep. No. 1444, *supra*, Pt. 1, at 6. Such a regime would also cause the precise threats to public health and safety that Congress sought to avert in passing the CSA. See 21 U.S.C. 801 (finding that "[t]he illegal * * * manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.").

The threat to the comprehensive nature of the CSA from an intrastate, personal use, or free distribution exception would be greater still for *a schedule I drug*, like marijuana, which Congress has found has *no* accepted medical use and may not be manufactured, distributed, or possessed under *any* circumstances, except as part of a strictly controlled research project. 21 U.S.C. 812(b), 823(f). Congress's efforts to control any trafficking in marijuana would be significantly undermined were Congress to lack the power to prevent the manufacture, free distribution, and related possession of marijuana from swelling the market, and thereby to make effective the exercise of its undeniable power to eradicate marijuana trafficking. Congress's purpose to prevent the social harms stemming from drug abuse similarly would be defeated were Congress to lack the power to prevent such activities. As Judge Beam concluded, "[i]f Congress cannot reach individual [marijuana] growers, possessors, and users, its overall statutory scheme will be totally undermined." Pet. App. 38a. This is clearly a situation in which the intrastate activities at issue not only "affect interstate commerce," but also "the exercise of Congress's power over it." *Darby*, 312 U.S. at 118. The regulation of such activities is, therefore, a necessary and proper means of ensuring the full accomplishment of the purposes of the CSA and the integrity of its closed system of distribution. See, *e.g.*, *Sabri*, 124 S. Ct. at 1946-1947; *Jinks*, 538 U.S. at 461-464.

D. The Ninth Circuit's Reliance On Respondents' Purported Medical Use Of Marijuana Is Seriously Flawed

The court of appeals apparently accepted the proposition that the CSA constitutionally applies to a broad class of activities that includes the commercial manufacture, distribution, and possession of controlled substances, including marijuana, whether these activities occur interstate or intrastate. Pet. App. 10a-11a. The court held, however, that the CSA could not constitutionally be applied to what it characterized as a "*separate and distinct class of activities*: the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law," *id.* at 11a, because the court of appeals did not perceive that class to involve economic activity or to have a substantial effect on interstate commerce, *id.* at 11a-12a, 16a-17a.

The court's reasoning rested on two equally mistaken premises. First, the court improperly excised a subclass of activities that cannot be divorced from the

general class of activities regulated by the CSA. Second, the court erroneously concluded that factors it believed to be unique to the assertedly medical use of marijuana as approved by a physician render Congress powerless to regulate the manufacture, free distribution, and possession of marijuana under the CSA when such activities occur for purported medical purposes.

1. Respondents are engaged in economic activity

The court's reliance on the non-commercial nature of respondents' conduct ignores the fact that the sort of drug activities in which respondents engage were reasonably determined by Congress to be part of the overall class of activities covered by the CSA—the manufacture, distribution, and possession of controlled substances—that unquestionably "involve[s] economic activity" and substantially affects commerce. *Lopez*, 514 U.S. at 560. Because the CSA is a "*general regulatory statute*" that "*bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under *that statute* is of no consequence." *Id.* at 558 (quoting *Wirtz*, 392 U.S. at 197 n.27) (last emphasis added). As the Second Circuit has explained in upholding the CSA as applied to the manufacture of marijuana without the intent to distribute it, "[t]he nexus to interstate commerce * * * is determined by the class of activities regulated by the statute as a whole, not by the simple act for which an individual defendant is convicted." *Proyect* v. *United States*, 101 F.3d 11, 13 (2d Cir. 1996); see *United States* v. *Davis*, 288 F.3d 359, 362 (8th Cir.) (sustaining application of CSA restriction on possession to a defendant's home manufacture of methamphetamine because the conduct constituted part of the "economic endeavor" compre-

hensively regulated by the statute), cert. denied, 537 U.S. 822 (2002); accord *United States* v. *Leshuk*, 65 F.3d 1105, 1112 (4th Cir. 1995). The Ninth Circuit accordingly erred in seizing on whether respondents' activities, in isolation, were non-commercial or had interstate effects, without ever considering whether Congress reasonably included respondents' activities as part of the overall class of drug activities regulated by the CSA in order to establish a comprehensive scheme of regulation of the market in controlled substances.

Moreover, as noted above (see pp. 21-22, *supra*) respondents' manufacturing, distribution, and possession activities themselves "involved economic activity" (*Lopez*, 514 U.S. at 560) to at least the same extent as Roscoe Filburn's home-grown production of wheat in *Wickard*. In both cases, the regulated individuals are producing a fungible commodity for which there is an established market and are doing so for their own use when they would otherwise be participants in a regulated market. Indeed, the Doe respondents are producing and distributing the commodity for *others*, but claim to distribute it free of charge. In *Wickard*, Filburn would have purchased his wheat in the open market to meet his needs. Likewise, in this case, persons such as respondents would presumably either purchase FDA-approved (and if listed, CSA-controlled) prescription drugs in the open market or purchase marijuana in the black market. Indeed, respondent Monson testified in this case that as a result of the DEA's seizure of her "medicinal [marijuana] plants," "I must now find a way to get my medicine *from another source*." J.A. 59 (emphasis added). Similarly, respondent Raich testified that she has previously obtained her marijuana from the Oakland Cannabis Buyers' Cooperative, a commercial distributor of marijuana, and

she also testified that after federal agents shut down that cooperative, "I was forced to obtain my medication *on the street*." J.A. 87 (emphasis added). More broadly, the prevailing conditions in the commercial market for wheat or marijuana influence the extent to which individuals self-produce or buy on the open market, and the activities of these individuals in turn affect the market. See *Lopez*, 514 U.S. at 560-561 (quoting *Wickard*, 317 U.S. at 128).

To be sure, in *Wickard*, the home-grown production competed with wheat in a *lawful* market that Congress sought to protect and stabilize, whereas marijuana is an illicit substance (except in the context of strictly controlled research projects) and therefore is distributed in an *unlawful* market. But there is nothing in the Court's Commerce Clause jurisprudence that suggests that Congress's power is weaker when a regulated product is particularly harmful and therefore illicit. The salient point is that for both the wheat in *Wickard* and the marijuana here, the commodity at issue is subject to a comprehensive scheme of regulation clearly within Congress's commerce power, and the activities of those who produce, possess, or distribute the commodity for personal use have economic impacts on the market in such a way as to interfere with Congress's attempt to regulate it.

The Ninth Circuit was accordingly wrong in deeming respondents' "limited [marijuana] use [as] clearly distinct" from the broader illicit commercial drug market because "the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." Pet. App. 11a. This Court in *Wickard*, and again in *Lopez*, rejected that very distinction. *Wickard* thus held that Congress could regulate home-grown manufacture of wheat that was not "sold or intended to

be sold," *Wickard*, 317 U.S. at 119, and that "may not be regarded as commerce." *Lopez*, 514 U.S. at 556 (quoting *Wickard*, 317 U.S. at 125). Indeed, the logic of the Ninth Circuit's distinction would prevent Congress from regulating the production and possession—*and even the free distribution*—of *any* controlled substance for *any* personal (including recreational) use, since in that situation, too, the drug "is not intended for, nor does it enter, the stream of commerce" (Pet. App. 11a), at least as the Ninth Circuit conceived of that stream. Thus, it is simply irrelevant that respondents' activities are not commercial in the sense of involving a transaction for consideration, since they do involve economic activity in a class that substantially affects both the market for controlled substances and the effectiveness and integrity of Congress's comprehensive program to regulate that market.

2. The purported medical purposes of respondents' activities do not remove the conduct from Congress's commerce power

The court of appeals also critically erred in relying on the fact that respondents' activities are for purported medical purposes and that Congress's findings in 21 U.S.C. 801 do not specifically address marijuana or the use of marijuana for those purposes. Pet. App. 11a, 19a. Congress's findings are directed at *all* controlled substances, which of course include marijuana. 21 U.S.C. 801, 812(c) (schedule I(c)(10) and (17)). Congress clearly had marijuana in mind in making those findings given Congress's prominent placement of marijuana in schedule I to be "subject to the most stringent controls" and Congress's awareness that marijuana was one of "the most widely abused drug[s]" in the country. H.R.

Rep. No. 1444, *supra*, Pt. 1, at 7, 13; accord S. Rep. No. 613, *supra*, at 2-4.

For purposes of defining Congress's power under the Commerce Clause in enacting the CSA, moreover, there is no basis for distinguishing marijuana production, distribution, or use for purported medicinal purposes, as opposed to recreational (or any other) purpose. To the contrary, as part of its comprehensive regulation of controlled substances, the CSA specifically speaks to the use of controlled substances for medical purposes and the role of physicians in approving their use. For example, whether a substance has an accepted medical use in treatment in the United States is one of the criteria for placement of a controlled substance in schedules I through V, 21 U.S.C. 812(b), and controlled substances generally may be manufactured, distributed, and possessed under the CSA, if at all, only for medical purposes. *E.g.*, 21 U.S.C. 802(21). And where there is an accepted medical use for a controlled substance, the manufacture and distribution of the drug may occur only within the closed regulatory scheme of the Act itself, because of the potential for abuse of and dependence on the drug.

The regulatory scheme imposes registration, labeling, packaging, production, and record-keeping requirements to maintain the safety and integrity of the program, 21 U.S.C. 822-827, and mandates a prescription for dispensing a drug if such a prescription is required by the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 829. Such regulation of the manufacturing and dispensing of drugs by pharmacies and others for medical use falls squarely within the scope of Congress's powers under the Commerce Clause. The Act also speaks to the role of physicians in dispensing controlled substances. It requires that they be registered under

the CSA to do so, and requires a physician's prescription for dispensing the drug, unless it is directly dispensed by the physician personally. 21 U.S.C. 829.

In short, neither the purported medical use of marijuana nor the role of a physician in approving it provides the slightest basis for excluding it from the comprehensive coverage of the CSA, any more than those factors would support excluding any other controlled substance from the Act. The class of conduct covered by the CSA unquestionably is subject to regulation by Congress under the Commerce Clause because it has a substantial effect on interstate commerce, and Congress plainly had a rational basis for including the manufacture, free distribution, and possession of marijuana for purported medical purposes within that class.

The court was of the view that "concern regarding users' health and safety is significantly different in the medicinal marijuana context, where the use is pursuant to a physician's recommendation," Pet. App. 11a, and that "the limited medicinal use of marijuana as recommended by a physician arguably does not raise the same policy concerns regarding the spread of drug abuse." *Ibid.* Congress has rejected those very propositions. The CSA specifies that marijuana, as a schedule I drug, has "no currently accepted medical use in treatment in the United States," a "high potential for abuse," and "a lack of accepted safety for use" even "under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C).[5]

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[5] The CSA contains provisions under which a controlled substance that has been placed in schedule I (or any other schedule) may be transferred to another schedule or entirely removed from the schedules. 21 U.S.C. 811. In 2001, DEA denied a petition to reschedule marijuana, based on an evaluation of the medical and scientific evidence demonstrating that marijuana continues to

Moreover, even for those controlled drugs that (unlike marijuana) have been determined to have an accepted medical use in treatment and therefore are listed in schedules II through V, the CSA imposes comprehensive restrictions on the manufacture, distribution, and possession of the drugs—including restrictions on physicians and pharmacies—in order to maintain the closed system of distribution and to protect the public health and safety. The court of appeals' decision, by contrast, would place marijuana—a schedule I substance—wholly outside those regulatory safeguards. Thus, the court of appeals' conclusion that the possession, manufacture, and free distribution of marijuana for purported personal "medicinal" use justify excluding those activities altogether from the reach of the CSA is flatly inconsistent with the fundamental premises and purposes of the CSA. Indeed, far from suggesting that the purported medical use of a drug is a basis for excluding it from the scope of regulation under the CSA as a matter of constitutional law, the medical setting for the use of a drug that is subject to abuse provides further justification for its regulation.

---

meet the criteria for placement in schedule I. 66 Fed. Reg. at 20,038. The DEA relied in significant part on the medical and scientific analysis by the Department of Health and Human Services (HHS), as well as HHS's conclusions that "[t]here are no FDA-approved marijuana products" and "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition." *Id.* at 20,051, 20,052. The DEA previously had rejected a petition to reschedule marijuana in 1992 (57 Fed. Reg. 10,499), and that denial was affirmed by the D.C. Circuit. *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (1994) ("[T]he Administrator's findings are supported by substantial evidence," including "the testimony of numerous experts that marijuana's medicinal value has never been proven in sound scientific studies.").

The court of appeals' reliance on the purported medical purposes of respondent's drug activities also is inconsistent with this Court's decision in *Oakland Cannabis*. In holding that the CSA forecloses a medical necessity defense to an enforcement action under the CSA, which the Ninth Circuit had embraced, the Court explained that the CSA

> reflects a determination that marijuana has no medical benefits worthy of an exception (outside the confines of a Government-approved research project). Whereas some other drugs can be dispensed and prescribed for medical use, see 21 U.S.C. § 829, the same is not true for marijuana. Indeed, for purposes of the Controlled Substances Act, marijuana has "no currently accepted medical use" at all.

532 U.S. at 491. The Court emphasized that, "[l]est there be any confusion, we clarify that nothing in our analysis, or the statute, suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act." *Id.* at 494 n.7. In short, the Ninth Circuit purports to give a Commerce Clause basis for effectively re-instating the medical necessity defense that the court of appeals previously adopted in *Oakland Cannabis* based on the same improper rejection of the congressional judgments embodied in the CSA. Because Congress's policy judgments respecting marijuana are reflected in a comprehensive drug statute that regulates the market in controlled substances, the CSA is constitutional as applied to respondents' drug manufacture, distribution, and possession.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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IN THE

Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

ANGEL McCLARY RAICH, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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QUESTION PRESENTED

Respondents are patients suffering from serious, painful, or life-threatening medical conditions, and caregivers to one of the patients, who possess or cultivate cannabis in California using only materials originating from or manufactured within that State. The cannabis is used solely by the patients, for medical purposes, as recommended by the patients' physicians and authorized by the California Compassionate Use Act, Cal. Health & Safety Code § 11362.5. The question presented is:

Whether Respondents are entitled to a preliminary injunction preventing Petitioners from taking action to enforce the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, against them based upon: (1) the findings of both courts below that the balance of hardships and the public interest tip sharply in favor of Respondents, such that a preliminary injunction is warranted based upon the existence of a serious question going to the merits; (2) the likelihood that Respondents will succeed on the merits of their claim that the Controlled Substances Act, if interpreted to apply to Respondents, exceeds Congress's power under the Commerce Clause; and (3) the likelihood that Respondents will succeed on the merits of their additional claims under the Due Process Clause of the Fifth Amendment, the Ninth and Tenth Amendments, and the medical necessity doctrine.

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States, and Karen P. Tandy, Administrator of the Drug Enforcement Administration.

Respondents are Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two.

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CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Commerce Clause (Article I, Section 8, Clause 3), the Due Process Clause of the Fifth Amendment, the Ninth Amendment, and the Tenth Amendment of the United States Constitution, and relevant provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA"), and the Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5 (West 2004), are reproduced at App. A, *infra*.

STATEMENT OF THE CASE

1. a. California is one of nine States that have enacted laws authorizing the use of cannabis for medical purposes. *See* Compassionate Use Act of 1996.[1] The purpose of the Compassionate Use Act is "[t]o ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where the medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief." Cal. Health & Safety Code § 11362.5(b)(1)(A). The Act permits a patient, or the patient's primary caregiver, to possess or cultivate cannabis solely for personal medical purposes of the patient upon the recommendation or approval of a physician. *Id.* § 11362.5(d). The Act expressly provides that it shall not "be construed to supersede legislation prohibiting persons from engaging in conduct that endangers

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[1] The other States are Alaska, Colorado, Hawaii, Maine, Nevada, Oregon, Vermont, and Washington. *See* App. B, *infra* (collecting citations). At least 26 States have taken steps in this direction. *See id.* This State legislation reflects strong popular support for allowing patients to use medical cannabis. *Id.* at 2b.

others, nor to condone the diversion of marijuana for nonmedical purposes." *Id.* § 11362.5(b)(2).[2]

b. The CSA makes it a federal crime to "possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice or except as otherwise authorized by this title." 21 U.S.C. § 844(a). The CSA defines a "practitioner" as "a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . ., to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. § 802(21). The CSA also provides that it should not be construed to "to ... exclu[de] any State law on the same subject matter ..., unless there is a positive conflict" between Federal and State law such that "the two cannot consistently stand together." 21 U.S.C. § 903.

c. For purposes of the CSA, marijuana is classified as a schedule I drug with "no currently accepted medical use in treatment in the United States," *id.* § 812(b)(1)(B), (c).[3] Despite this classification, "the public record reflect[s] a legitimate and growing division of informed opinion on this issue." *Conant v. Walters*, 309 F.3d 629, 640 (9th Cir. 2002) (Kozinski, J., concurring), *cert. denied*, 124 S. Ct. 387 (2003). "A surprising number of health care professionals and organizations have concluded that the use of marijuana may be appropriate for a small class of patients who do not respond well to, or do not tolerate, available prescription drugs." *Id.* at 640-41. A report commissioned by the White House Office of National Drug Control Policy and carried out by the Institute of Medicine, the medical component of the National Academy of Sciences, concluded that "the accumulated data suggest a variety of indications, particularly for pain relief, antiemesis, and appetite stimulation," and that "[f]or patients such as those . . . who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication." Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base* 177 (Janet E. Joy *et al.* eds., 1999) ("IOM Report"), *available at* http://www.nap.edu/books/0309071550/html. The IOM Report also concluded that currently "there is no clear alternative for people suffering from *chronic* conditions that might be relieved by smoking marijuana, such as pain and AIDS wasting." *Id.* at 179 (emphasis in original). Accordingly, the IOM Report endorsed treatment of such patients with smoked cannabis subject to an oversight mechanism. *See id.* Other reputable scientific and governmental bodies have reached similar conclusions. *See Conant*, 309 F.3d at 640-43 (Kozinski, J., concurring) (summarizing scientific evidence supporting medical use of cannabis, and its acceptance by, among others, the British House of Lords and the Canadian government).[4]

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[2] California recently enacted additional legislation to clarify the scope of the Compassionate Use Act. The new legislation establishes a voluntary program under which the State will issue identification cards to qualified patients who satisfy State legal requirements. *See* S.B. 420 (Cal. 2003), codified at Cal. Health & Safety Code §§ 11362.7-11362.83 (2003).

[3] Federal law defines "marihuana" to mean "all parts of the plant Cannabis sativa L" except "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, . . . or the sterilized seed of such plant." 21 U.S.C. § 802(16). In this brief, the term "cannabis" refers to any part of the plant Cannabis sativa L used for medical purposes.

[4] Petitioners' brief does not acknowledge any of this evidence. Instead, Petitioners quote, without qualification, statements that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition" and "there are no FDA-approved marijuana (...continued)

2. Respondents are California citizens who cultivate or use cannabis for medical treatment as recommended by a physician pursuant to the Compassionate Use Act. Pet. App. 46a. Respondents Angel Raich and Diane Monson each suffer from serious medical conditions. Both courts below found that "[t]raditional medicine has utterly failed these women." *Id.* at 5a, 46a. Respondents John Doe Number One and John Doe Number Two are Raich's caregivers.

a. Respondent Raich suffers from a daunting array of medical conditions including "life-threatening weight loss, nausea, severe chronic pain (from scoliosis, temporomandibular joint dysfunction and bruxism, endometriosis, headache, rotator cuff syndrome, uterine fibroid tumor causing severe dysmenorrheal, chronic pain combined with an episode of paralysis that confined her to a wheelchair), post-traumatic stress disorder, non-epileptic seizures, fibromyalgia, inoperable brain tumor (probable meningioma or Schwannoma), paralysis on at least one occasion (the diagnosis of multiple sclerosis has been considered), multiple chemical sensitivities, allergies, and asthma." J.A. 48 (Decl. of Frank Henry Lucido, M.D.). Raich's physician, a Board-certified family practitioner, states that she "has tried essentially all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects." J.A. 49. Raich's physician has provided a list of 35 medications that Raich has tried, all of which "resulted in unacceptable adverse side effects." *Id.* at 49-50. Raich's physician has determined that his patient "has no reasonable legal alternative to cannabis for effective treatment or alleviation of her medical conditions or symptoms." *Id.* at 49.

From 1996 to 1999, Raich was partially paralyzed and confined to a wheelchair. J.A. 63, 73-76 (Decl. of Angel Raich). In August 1997, after her physician concluded that her pain could not be controlled using conventional medications, Raich attempted suicide to end her pain and suffering. *Id.* at 76, 41. Thereafter, Raich began using cannabis on her physician's recommendation, and her medical condition improved significantly. J.A. 87. She is no longer confined to a wheelchair. *Id.* at 74-75. She is better able to cope with her medical conditions and plays a more active role in the lives of her two children. *Id.* at 88, 90-94.

Raich's physician has concluded that she may suffer rapid death if she is denied medical cannabis. J.A. 51 ("It could very well be fatal for Angel to forego cannabis treatments."). "It is [his] opinion that Angel cannot be without cannabis as medicine because of the precipitous medical deterioration that would quickly develop." *Id.* at 48. "Angel becomes debilitated from severe chronic pain." *Id.* "[S]he clearly loses weight, and would risk wasting syndrome and death, without cannabis." *Id.*[5]

b. Respondent Monson suffers severe, chronic back pain and constant painful muscle spasms caused by a degenerative disease of the spine. J.A. 53 (Decl. of John Rose, M.D.). Her physician, also a Board-certified family practitioner, states that "Diane has tried other medical alternatives to

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products." Pet. Br. 41-42 n.5 (quoting 66 Fed. Reg. 20,038 (Apr. 18, 2001)). In fact, Marinol is an FDA-approved product, and the active ingredient of Marinol is the cannabinoid THC, one of the psychoactive compounds in cannabis. *See* IOM Report 137, 202-07. Not all patients can tolerate Marinol, and "[i]t is well recognized that Marinol's oral route of administration hampers its effectiveness because of slow absorption and patients' desire for more control over dosing." *Id.* at 205-06.

[5] Petitioners refer in this Court to Respondents' "purported personal 'medicinal' use" of marijuana. *See* Pet. Br. I. Respondents and their physicians have submitted sworn statements that Respondents are using cannabis for medical purposes, in accordance with California law. Petitioners have not disputed that evidence and, at this interlocutory stage of the proceedings, must therefore accept the record as it stands.

medical cannabis, including Flexeril, a muscle relaxant, and Feldene, a p erful anti-inflammatory," but "those prescription drugs have proven to be either ineffective in relieving Diane's pain and suffering or produce intolerable side effects." *Id.* Dr. Rose "prescribed Vicodin and Vioxx to attempt to relieve Diane's pain and suffering," but "Vicodin, an addictive drug," leaves her with an "extremely sick stomach . . . for several days after any use." *Id.* Vioxx "appears to relieve Diane's inflammation associated with her back pain" but "does not relieve her painful spasms." *Id.* Dr. Rose determined "that medical cannabis use is deemed appropriate for Diane Monson, and that medical cannabis provides necessary relief for Diane's pain and suffering." *Id.* Accordingly, "pursuant to California State law, medical cannabis was recommended for Diane as treatment of her medical conditions, including her Chronic Back Pain and Spasms." *Id.* Cannabis "virtually eliminates" Diane's muscle spasms and "greatly relieves" her back pain. *Id.* at 58 (Decl. of Diane Monson). Without cannabis, Monson would suffer "intense," "debilitating" pain that would make working and sitting down "impossible," and would relegate her to lying down. *Id.*

c. Raich's cannabis is grown using only soil, water, nutrients, equipment, supplies, and lumber originating from or manufactured within California. Pet. App. 47a. Monson's "cultivation of marijuana is similarly local in nature." *Id.* Monson cultivates her own cannabis. *Id.* at 46a. Raich is unable to cultivate cannabis. *Id.*; J.A. 87-88. Raich therefore relies on two caregivers, Respondents John Doe Number One and John Doe Number Two, to cultivate it for her. Pet. App. 5a, 46a; J.A. 87-90. Raich processes some of the plants into cannabis oils, balm, and foods. J.A. 90-91. Raich's caregivers grow her cannabis specifically for her, pursuant to her instructions and on her physician's written recommendation. *Id.* at 88-89. The caregivers cultivate Raich's cannabis completely free of charge. *Id.* at 88.[6]

d. On August 15, 2002, deputies from the Butte County Sheriff's Department and agents from the Drug Enforcement Administration ("DEA") came to Monson's home, where they found six cannabis plants. Pet. App. 6a. The deputies concluded that Monson's use of cannabis was legal under the Compassionate Use Act. *Id.* Following a three-hour standoff involving the Butte County District Attorney and the U.S. Attorney for the Eastern District of California, the DEA agents seized and destroyed Monson's cannabis plants. *Id.*

3. Respondents brought this action contending that applying the CSA to prevent them from possessing and cultivating cannabis for personal medical purposes, as recommended by their physicians and permitted by State law, would violate the Commerce Clause, the Due Process Clause of the Fifth Amendment, the Ninth Amendment, the Tenth Amendment, and the doctrine of medical necessity. The district court found that the balance of hardships and the public interest tip sharply in favor of granting Respondents injunctive relief. Pet. App. 67a-68a (the interests asserted by Petitioners "wane in comparison with the public interests enumerated by plaintiffs and by the harm that they would

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[6] Although Petitioners assert that the activities at issue in this case include "the distribution of marijuana," Pet. Br. I, the CSA defines "distribute" to mean "to deliver (other than by administering or dispensing)," and defines "dispense," in turn, as "to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of, a practitioner." 21 U.S.C. § 802(10), (11). Monson cultivates cannabis for her own use. There clearly is no "distribution" in her case. Raich's caregivers, acting pursuant to a practitioner's recommendation authorized by California law, "dispense" her medication. It is therefore a significant stretch to say that there is any delivery of a controlled substance. Moreover, cultivating a neighbor's vegetable garden is not the same as distributing the vegetables.

suffer if denied medical marijuana"; Respondents have submitted "strong evidence that [they] will suffer severe harm and hardship if denied use of [cannabis]"). The district court nevertheless denied Respondents' motion for a preliminary injunction, on the ground that they were "unable, on this record, to establish the required 'irreducible minimum' of a likelihood of success on the merits." *Id.* at App. 68a.

4. The court of appeals reversed. It agreed with the district court that "[t]here can be no doubt on the record as to the significant hardship that will be imposed on the patient-appellants if they are denied a preliminary injunction," noting that Petitioners "do not dispute this." *Id.* at 24a. The court found that Petitioners' interests are "weak in comparison to the real medical emergency facing the patient-appellants in this case," *id.* at 26a, and that "[t]he public interest of the state of California and its voters in the viability of the Compassionate Use Act also weighs against the [Petitioners'] concerns," *id.* at 25a.

The court of appeals determined that Respondents are likely to prevail on the merits of their claim that the CSA, as applied to them, exceeds Congress' Commerce Power. Pet. App. 23a. The court noted that "the way in which the activity or class of activities is defined is critical." *Id.* at 11a. The court determined that "the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician" should be considered a distinct class of activity, separate from drug trafficking. *Id.* The court observed that "concern regarding users' health and safety is significantly different in the medical marijuana context, where the use is pursuant to a physician's recommendation"; "limited medical use of marijuana as recommended by a physician arguably does not raise the same policy concerns regarding the spread of drug abuse"; and "this limited use is clearly distinct from the broader illicit drug market – as well as any broader

commercial market for medical marijuana – insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." *Id.*

Applying the four-factor analysis in *United States v. Morrison*, 529 U.S. 598 (2000), the court held that the cultivation, possession, and use of cannabis for medical purposes is not properly characterized as commercial or economic activity because it does not involve an "'exchange of goods and services, esp. on a large scale involving transportation between cities, states, and nations.'" Pet. App. 14a (quoting *Black's Legal Dictionary* (7th ed. 1999) (defining "commerce")). *Second*, the CSA lacks a "jurisdictional hook" that would limit it to "cases that substantially affect interstate commerce." *Id.* 18a. *Third*, although the CSA includes general findings concerning the effects of intrastate activity on interstate commerce, those findings "are not specific to marijuana, much less intrastate medicinal use of marijuana that is not bought or sold and the use of which is based on the recommendation of a physician." *Id.* at 19a. *Fourth*, "the link between the regulated activity and a substantial effect on interstate commerce is 'attenuated.'" *Id.* at 20a. Even if the intrastate cultivation, possession, and use of medical cannabis on the recommendation of a physician could affect interstate commerce "at the margins," the court found, "[i]t is far from clear that such an effect would be substantial." *Id.* at 21a-22a.

Judge Beam dissented. *Id.* 26a-43a. He questioned whether Respondents' claims are ripe and whether they have standing to pursue this action. *Id.* at 27a. On the merits, Judge Beam concluded that "[i]t is simply impossible to distinguish" this case from *Wickard v. Filburn*, 317 U.S. 111 (1942). *Id.* at 26a.

SUMMARY OF ARGUMENT

This case is and always has been about federalism and State sovereignty. It is therefore remarkable that the word "federalism" does not appear in Petitioners' brief. This striking omission reveals the fatal weakness in Petitioners' analysis of the constitutional issues confronting the Court. When one considers principles of federalism and State sovereignty in the light of this Court's previous decisions, it is clear that either the CSA should not be interpreted to apply to Respondents' conduct (*see* Part III below), or the CSA if so interpreted exceeds Congress' Commerce Power as applied to Respondents.

This case, like prior Commerce Clause cases, "requires the Court . . . to appreciate the significance of federalism in the whole structure of the Constitution." *United States v. Lopez*, 514 U.S. 549, 575 (1995) (Kennedy, J., concurring). In prior cases, the Court has held that the Federal Government exceeded its Commerce Power by "criminalizing conduct already denounced as criminal by the States." *Id.* at 561 n.3. In this case, the issue is whether the Federal Government may criminalize wholly intrastate, noncommercial conduct that is expressly authorized and supervised by a State exercising its core police powers to preserve the lives of its citizens and reduce their pain and suffering.

Petitioners' argument goes beyond the outer limits of *Wickard v. Filburn*, which involved regulation of commercial farming activity. If the Court upholds Petitioners' claim of federal power, this case will supplant *Wickard* to become the most expansive interpretation of the Commerce Clause since the Founding, and this Court's landmark decisions in *Lopez* and *Morrison* will become dead letters.

This case is an as-applied challenge under the Commerce Clause. This Court has always entertained such challenges. The relevant class of activity for purposes of this

challenge is the activity Respondents are actually engaged in, activity that is defined by State law. *Morrison*'s four "reference points" each indicate that the Commerce Power does not reach this far: (i) Respondents' activity is not commercial in nature; (ii) the CSA lacks a jurisdictional element; (iii) the generalized findings in the CSA do not support application of that Act to medical use of cannabis that is authorized and supervised by a State; and (iv) the link between Respondents' activities and interstate commerce is, at best, attenuated. In addition, prohibiting Respondents' activities is not essential to a larger regulation of interstate economic activity.

Applying the CSA to Respondents would contravene basic principles of federalism and State sovereignty. States possess broad powers to define criminal law, regulate medical practice, and protect the lives of their citizens. In *Lopez* and *Morrison*, the Court invalidated federal statutes that were consistent with achievement of goals shared by all the States. In this case, application of the CSA to Respondents would foreclose achievement of the State's substantive goal. Principles of federalism and State sovereignty have led the Court, in cases such as *Parker v. Brown*, 317 U.S. 341 (1943), and *Gregory v. Ashcroft*, 501 U.S. 452 (1991), to interpret federal laws as inapplicable to conduct that is authorized and supervised by a State or that involves the States' historic powers.

There are also additional grounds for affirmance. This case presents the "difficult issue" of whether the doctrine of "necessity is available to a seriously ill patient for whom there is no alternative means of avoiding starvation or extraordinary suffering," *United States v. Oakland Cannabis Buyer's Coop.*, 532 U.S. 483, 501 (2001) (Stevens, J., concurring in the judgment), and that alone is sufficient to uphold the preliminary injunction. In addition, Respondents have presented serious questions concerning due process, liberty, and fundamental rights.

ARGUMENT

I. THE COMMERCE POWER DOES NOT EXTEND TO REGULATION OF PATIENTS WHO USE LOCALLY CULTIVATED CANNABIS FOR MEDICAL PURPOSES, AS RECOMMENDED BY A PHYSICIAN AND AUTHORIZED BY STATE LAW.

This Court has "emphasized" that "Congress' regulatory authority" under the Commerce Clause "is not without effective bounds," *United States v. Morrison*, 529 U.S. 598, 608 (2000), and "'may not be extended . . . [to] effectually obliterate the distinction between what is national and what is local and create a completely centralized government,'" *Lopez*, 514 U.S. at 556-57 (1995) (quoting *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37 (1937)). In this case, the Court is called upon to reaffirm once again that the Commerce Clause places effective limits on the power of the central government. As in *Morrison* and *Lopez*, Petitioners make no attempt to defend the federal statute at issue based on "use of the channels of interstate commerce," "the instrumentalities of interstate commerce, or persons or things in interstate commerce." *Morrison*, 529 U.S. at 609 (internal quotations and citations omitted). Accordingly, application of the CSA to Respondents can be justified, if at all, only on the ground that Respondents' activities "substantially affect interstate commerce." *Id.*

A. Petitioners Seek To Expand The Commerce Power Substantially Beyond The Limits Of *Wickard*.

Should the Court rule for Petitioners, this case would immediately replace *Wickard v. Filburn*, 317 U.S. 111 (1942) as "the most far reaching example of Commerce Clause authority over intrastate activity." *Lopez*, 514 U.S. at 561. Over the years, *Wickard* has been subjected to powerful criticism. *See, e.g., Lopez*, 514 U.S. at 594, 602 (Thomas, J., concurring) (concluding that *Wickard* misconstrued *Gibbons v. Ogden*, 9 Wheat. 1 (1824), and stating, "At an appropriate juncture . . . we must modify our Commerce Clause jurisprudence"). If the Court were to conclude that *Wickard* is controlling, this case would indeed be an "appropriate juncture" to consider whether *Wickard* extended Congress' Commerce Power beyond its proper boundaries. *See* Amicus Br. of Institute of Justice (arguing that *Wickard* should be reconsidered). In fact, *Wickard* differs substantially from this case. Properly understood, it supports a decision for Respondents.

Wickard was a challenge to the Agricultural Adjustment Act of 1938 ("AAA"), a statute that authorized the Secretary of Agriculture to limit the number of acres of wheat planted by farmers in order to "control the volume [of wheat] moving in interstate and foreign commerce." 317 U.S. at 115. The plaintiff, Roscoe Filburn, owned a farm in Ohio, "maintaining a herd of dairy cattle, selling milk, raising poultry, . . . selling poultry and eggs," and growing wheat. *Id.* at 114. Filburn's practice was "to sell a portion of the [wheat] crop; to feed part to poultry and livestock on the farm, some of which is sold; to use some in making flour for home consumption; and to keep the rest for the following seeding." *Id.* In 1941, Filburn exceeded his acreage allotment under the AAA. *Id.* at 114-15. He refused to pay a penalty or turn the excess wheat production over to the government for storage, contending the AAA was an improper regulation of "production" rather than "commerce."

In upholding application of the AAA to Filburn, the Court held that Commerce Clause analysis does not turn on "nomenclature" (*e.g.*, whether to classify the activity in question as "production"), but instead requires "consideration of the actual effects of the activity in question upon interstate commerce." *Id.* at 120. The Court was able to consider these "actual effects," because the parties "stipulated a summary of the economics of the wheat industry." *Id.* at 125. The Court

relied on this evidence to conclude that while "[t]he total amount of wheat consumed as food varies but relatively little, and use as seed is relatively constant," "[c]onsumption on the farm where grown appears to vary in an amount greater than 20 per cent of average production." *Id.* at 127. "It can hardly be denied," the Court concluded, "that a factor of such volume and variability as home-consumed wheat would have a substantial influence on price and market conditions." *Id.* at 128.[7]

Wickard differs from this case in at least three respects. *First*, the AAA, unlike the CSA, exempted small farming operations – and thus, contrary to Petitioners' assertion (Pet. Br. 37), did not apply to every person who "produced a fungible commodity for which there is an established market." When the wheat at issue in *Wickard* was planted, the AAA exempted "small producers" who produced "less than 200 bushels" (about *six tons*) of wheat. *See* 317 U.S. at 130 & n.30. By the time the wheat was harvested, the AAA had been amended to exempt up to 15 acres, enough to produce 300 bushels (about *nine tons*) of wheat. *See* 54 Stat. 232. Consequently, families who grew wheat only for their own personal use – even large families who consumed large amounts of wheat – were not subject to the AAA at all. *Wickard* thus did not present the question of whether the Commerce Power extends to regulating agricultural products produced in small amounts for home consumption. This case *does* present that question, because the CSA, unlike the AAA, contains no exemption for small quantities intended

[7] The Court's statement that wheat consumed on the farm could be regulated notwithstanding that it "may not be regarded as commerce," *Wickard*, 317 U.S. at 125, was made in the context of its rejection of previous holdings excluding "production" from the scope of the Commerce Clause. Thus, this statement should not be understood as authorizing Congress to regulate noneconomic local activity.

for personal use. *Wickard* is in no way controlling of this question.

Second, *Wickard*, unlike this case, involved a quintessential economic activity – a commercial farming operation. Filburn's farm produced substantial quantities of wheat for sale in the market and for use as an input to produce other agricultural products destined for sale. The farm's "wheat acreage allotment" for 1941 under the AAA was 11.1 acres, which at a "normal yield" of "20.1 bushels of wheat an acre," *Wickard*, 317 U.S. at 114, yielded 221 bushels of wheat. A bushel of wheat weighs about 60 pounds,[8] so the farm was expected to produce, and authorized to sell, 13,260 pounds – or over 6.6 *tons* – of wheat without penalty. Filburn actually planted 23 acres of wheat – twice the allotted amount. *Id.* The 11.9 excess acres produced 239 bushels of wheat, bringing the farm's total wheat production to 460 bushels (or 13.8 *tons*). *Id.*

"Contemporary lawyers often believe that Roscoe Filburn converted his excess wheat into home-baked loaves of bread." Jim Chen, *Filburn's Legacy*, 52 Emory L.J. 1719, 1759 (2003). A careful study of *Wickard* shows this to be a misconception. In addition to the facts recited above, the Solicitor General's brief in *Wickard* stated that wheat consumed on farms was used "as feed for livestock" and "as seed," but only "to a slight extent, as food" for the farmer's family. U.S. Br. in *Wickard* at 41. Simple arithmetic confirms this. "To consume the 239 excess bushels at issue in the July 1941 wheat harvest, the Filburns would have had to consume nearly forty-four one-pound loaves of bread each day for the following year." Chen, *supra*, at 1759. In fact,

[8] *See* Wheat Foods Council, *Grains of Truth About Wheat*, *available at* http://www.wheatfoods.org/docs/Grains_Truth_Wheat_Facts.doc (last visited Oct. 10, 2004).

the vast majority of the farm's wheat production supported the farm's commercial operations, rather than feeding the farmer and his family.[9]

Unlike Roscoe Filburn, Respondents are not engaged in commercial farming. The cannabis at issue is not sold, bartered, exchanged, or used as an input to produce any other product that Respondents sell, barter, or exchange. Diane Monson cultivates only enough cannabis for her own medical use. Angel Raich's caregivers cultivate enough cannabis for her own medical use, without any charge, for compassionate rather than economic reasons. In contrast to *Wickard*, the quantities involved are minuscule and detached from any market. They are not part of a "home grown" crop principally intended for use in a commercial farming operation whose output will compete in the marketplace with, or enter into, interstate commerce.

Third, the Court in *Wickard*, having rejected a formalistic reliance in nomenclature, required *proof* of the actual effect of the regulated activity on interstate commerce. The Federal Government met this requirement by introducing detailed evidence showing that the activity of Filburn and other similarly situated farmers had a substantial aggregate effect on interstate commerce. As the government's brief explained, *in the years immediately before Congress enacted the AAA, nearly 30 percent of the nation's wheat was used on the farm where it was grown*. *See* U.S. Br. on Reargument in *Wickard* at 12.[10] The amount of wheat consumed on the farm also varied substantially from year to year, resulting in substantial effects on supply, demand, and prices. The Court's opinion in *Wickard* left no doubt that proof of the aggregate effect of this economic activity on interstate commerce was critical to the Court's decision. *See Wickard*, 317 U.S. at 128 ("It can hardly be denied that *a factor of such volume and variability* as home-consumed wheat would have a substantial influence on price and market conditions.") (emphasis added), *quoted in Lopez*, 514 U.S. at 560.

Setting aside for the moment the fact that Respondents' activity is noneconomic in nature, and therefore should not be subject to a *Wickard* "aggregate effects" analysis, *see infra* pp. 23-27, there exists no evidence in this case that the cultivation of cannabis solely for the personal medical use of seriously ill individuals, as recommended by their physicians and authorized by State law, has *any* aggregate effect on interstate commerce, much less a *substantial* effect. Medical cannabis patients grow and consume cannabis to meet their own personal medical needs and operate outside of any market. Further, they are "[r]elatively few" in number. *See* GAO, *Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes* 21 (Nov. 2002), *available at* http://www.gao.gov/new.items/d03189.pdf (In Alaska, Hawaii and Oregon "the number of participants registered was 0.05 percent or less of the total population of each respective state."). Although the GAO's report does not include statewide data for California, it does include data for four California counties. In each of these counties, cannabis

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[9] Between 1931 and 1936, the total average production of wheat in the United States was approximately 680.6 million bushels. U.S. Br. in *Wickard* at 12. "The amount of wheat consumed as livestock feed on the farm where grown ... ranged from 28 million bushels . . . to 174 million" bushels, *i.e.*, between 4.5% and 28.6% of total production. U.S. Br. on Reargument in *Wickard* at 4. "The amount of wheat used for seed ... ranged from a low of 73 million bushels . . . to a high of 97 million bushels," *i.e.*, between 12% and 15.9% of total production. *Id.* In contrast, "[t]he amount consumed as food by persons on the farm where grown" "stayed consistently between 11 and 16 million bushels," *i.e.*, between 1.8% to 2.6% of total production. *Id.*

[10] By the time the Court decided Wickard, the percentage had dropped, but it still accounted for 22 percent of wheat produced nationwide in 1940. U.S. Br. on Reargument in *Wickard* at 3.

patients represent less than one-half of one percent of the population.[11] Medical cannabis patients' activities, in the aggregate, are minuscule by comparison to the national market for marijuana, which, according to Petitioners (Pet. Br. 19), totaled approximately $10.5 billion in 2000.

This case is thus quite different from *Wickard*, where consumption by the regulated enterprise and similarly-situated enterprises accounted for about one-fourth of the nationwide wheat supply, and farmers readily shifted back and forth between marketing their wheat and feeding it to farm animals, so that applying the AAA to all commercial farms above a specified size was "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561.[12]

[11] This is so even though one of the four jurisdictions is San Francisco County, a county with an especially large number of AIDS patients.

[12] There are other pertinent differences between this case and *Wickard*. The AAA, unlike the CSA, did not conflict with a State law enacted to preserve the lives and health of the State's citizens. *Wickard* would be more closely on point if Congress had sought to displace a State law that authorized farmer Filburn to grow sufficient wheat to preserve the lives and health of his family in a time of economic depression. But no such State law existed (or was needed), and Congress was claiming no such power. In addition: (i) farmer Filburn *benefited* from the marketing quotas, which increased the price of his wheat; (ii) in a national referendum of wheat growers, 81% *voted for* the quotas, 317 U.S. at 116; and (iii) farmer Filburn faced only a $117.11 fine, *id.* at 115. Here, in contrast: (a) both courts below found that the CSA would severely *harm* Respondents; (b) the citizens of California *voted to permit* limited medical use of cannabis; and (c) Respondents face not a modest fine, but rather arrest, imprisonment, large fines and property forfeitures, severe pain and suffering, and even death.

B. The Relevant Class of Conduct In This Case Is Intrastate Medical Cannabis Activity Authorized By State Law And Recommended By A Physician.

Respondents are not challenging the constitutionality of the CSA on its face but only as it applies to the class of activities in which they are engaged. This Court "has always entertained" such challenges. *United States v. Stewart*, 348 F.2d 1132, 1141 (9th Cir. 2003); *accord United States v. Maxwell*, 2004 U.S. App. LEXIS 20610, *68 (11th Cir. Oct. 1, 2004). *Wickard* itself was an as-applied challenge. "Had the Court deemed regulation of the business of agriculture a sufficient basis for upholding the application of the [AAA] to Filburn, there would have been no need for it to analyze how his particular activities affected interstate commerce." *Stewart*, 348 F.2d at 1142. Similarly, in considering whether Title II of the Civil Rights Act exceeded Congress' powers under the Commerce Clause, the Court separately considered whether the statute was valid "as applied . . . to a motel which concededly serves interstate travelers," *Heart of Atlanta Motel Inc. v. United States*, 379 U.S. 241, 261 (1964), and "as applied to a restaurant annually receiving about $70,000 worth of food which has moved in commerce," *Katzenbach v. McClung*, 379 U.S. 294, 298 (1964). If the Court had considered only the entire class of activities covered by Title II, it would not have inquired into "whether a single hotel or restaurant had a sufficient nexus to interstate commerce, and thus could be federally regulated." *Stewart*, 348 F.3d at 1141-42. *See also Solid Waste Agency v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001) (to address Commerce Clause question, Court "would have to evaluate the precise object or activity that, in the aggregate, substantially affects interstate commerce").

If Commerce Clause challenges were decided based on whether the category of conduct described by the statute substantially affects interstate commerce, there could be no

as-applied challenges under the Commerce Clause, and this Court's decisions entertaining such challenges would be overruled. Facial challenges, too, would always fail so long as a portion of the regulated activities were within the powers of Congress. *Lopez* would then be reduced to a sport case in which Congress foolishly attempted to reach *only* a class of activities that, on its face, was wholly outside its power. Adopting this position would move the Court beyond the fringes of *Wickard* and effectively confer on Congress a general police power. This result can be avoided only if the courts, not Congress, determine the relevant class of activities for purposes of Commerce Clause analysis.

In prior Commerce Clause cases, the Court has looked to the nature of the activities actually engaged in by the parties before the Court. *See, e.g., Wickard*; *Heart of Atlanta Motel*. In this case, however, the Court can also look to an objective source other than the actual activity of the litigants: State law. California has enacted a statute that specifies an appropriate class of activity for purposes of as-applied analysis under the Commerce Clause: *the intrastate possession or cultivation of cannabis by a patient, or the patient's primary caregiver, solely for the patient's medical use, as recommended by a State-licensed physician and authorized by State law*. Because a State has delimited this class of activities by statute, the Court need not consider a classification proposed by individual litigants, or based solely on their own activities, so long as those activities fall within the State-defined class.[13]

Looking to State law to define the relevant class of activities in this case is consistent with basic constitutional

[13] Indeed, the CSA itself distinguishes between medical and non-medical uses of controlled substances. *See* Amicus Br. of Constitutional Law Scholars at 16-21.

doctrines concerning the relationship between the Federal Government and the States. It gives appropriate weight to the principles of federalism that inform this Court's Commerce Clause decisions. *See Morrison*, 529 U.S. at 617-19; *Lopez*, 514 U.S. at 567-68. It is also consistent with the Supremacy Clause, which provides that State law must give way to a *valid* exercise of federal power. Here, however, the question is *whether* the exercise of federal power is valid. To answer it, a court must identify the relevant class of activity, which here derives from a State exercising its police power.[14]

Apart from defining the relevant class, the fact that a sovereign State permits and regulates a class of activity also bears on a substantial effects analysis. For example, as discussed, *infra*, pp. 36-37, the existence and enforcement of statutorily-defined limits on the permitted class of activity may eliminate entirely any effect on interstate commerce or render any such effect trivial and insubstantial. That California has limited and regulates the conduct at issue in this case prevents that conduct from having a substantial effect outside California. In contrast, the cultivation or possession of cannabis in States that have not authorized it for medical use and do not regulate it would involve a factually distinct class of activity with a potentially different impact on interstate commerce. Similarly, cases involving illegal and unmonitored recreational uses of marijuana present significantly different issues that would markedly affect whether such activity is within Congress' Commerce Power.

[14] Respondents are not claiming that the States may limit in any way federal power under the Constitution. Notwithstanding that State law permits a given class of activity, the class would still be within the scope of the Commerce Power if it consisted of economic activity that in the aggregate substantially affects interstate commerce. *See, e.g., Wickard.*

Although Petitioners never clearly articulate their view of how to define the class of activity for Commerce Clause analysis, they appear to assert that the relevant conduct is "the overall class of activities covered by the CSA – the manufacture, distribution, and possession of controlled substances." Pet. Br. 36. *See also id.* at 37. If the Court were to accept this argument, it would put an end to any judicially-enforceable limit on the reach of the Commerce Clause power, and the line drawn by the Court in *Lopez* and *Morrison* would be obliterated. "[O]ne always can draw the circle broadly enough to cover an activity that, when taken in isolation, would not have substantial effects on commerce." *Lopez*, 514 U.S. at 600 (Thomas, J., concurring). If Congress could define the class of activity, there would be nothing it could not regulate. *See Morrison*, 529 U.S. at 657 (Breyer, J., dissenting) (noting that if Commerce Clause analysis depends on the class of activities addressed by the federal statute, Congress could reverse the result in *Morrison* simply by incorporating VAWA "in a broader 'Safe Transport' or 'Workplace Safety' act"). By the same reasoning, Congress could enact a "Controlled Property Act," purporting to reach all privately-owned goods in the United States because, in the aggregate, the possession of property is "a class of activities" that "substantially affects interstate commerce." In *Lopez* and *Morrison*, this Court rejected reasoning under which "Commerce Clause authority would effectively know no limit." *Sabri v. United States*, 124 S. Ct. 1941, 1947 (2004). It should do so here as well.

Petitioners thus ignore the central issue facing the Court when they assert: "For purposes of defining Congress' power under the Commerce Clause *in enacting* the CSA, . . . there is no basis for distinguishing marijuana production, distribution, or other use for purported medicinal purposes, as opposed to recreational (or any other) purpose." Pet. Br. 40 (emphasis added). Respondents do not challenge the power of Congress "to enact" the CSA. They challenge the

CSA only *as applied* to their activities. In such a challenge, the existence of the Compassionate Use Act makes it necessary to consider the class of activity defined and authorized by State law, separate and apart from other activity.

C. *Morrison*'s "Reference Points" Indicate That The Commerce Power Does Not Extend To Personal Cultivation Or Use Of Cannabis Authorized By State Law And Recommended By A Physician.

A proper definition of the class of activity at issue, as well as an understanding of differences between this case and *Wickard*, clarifies analysis of the four "reference points" this Court has considered in determining whether prohibiting an activity "exceed[s] Congress' authority under the Commerce Clause": whether (1) the conduct at issue is "economic" or part of "some sort of economic endeavor"; (2) the federal statute contains an "express jurisdictional element which might limit its reach to a discrete set of . . . possessions that additionally have an explicit connection with or effect on interstate commerce"; (3) there are "express congressional findings regarding the effects upon interstate commerce" of the activity in question; and (4) "the link between [the activity] and a substantial effect on interstate commerce [i]s attenuated." *Morrison*, 529 U.S. at 609-13. Properly analyzed, each "reference point" favors Respondents.

1. Respondents' activities are not economic or part of an economic endeavor.

In each case in which this Court has upheld federal regulation of an activity based upon its substantial effect on interstate commerce, "the activity in question has been some sort of economic endeavor." *Morrison*, 529 U.S. at 611; *see also id.* at 611 n.4 (intrastate activities held to be within the Commerce Power have "apparent commercial character"); *id.* at 613 ("thus far in our Nation's history our cases have upheld Commerce Clause regulation of intrastate activity

only where that activity is economic in nature"). *See, e.g.*, *Hodel v. Virginia Surface Mining & Reclamation Assoc., Inc.*, 452 U.S. 264 (1981) (coal mining); *Perez v. United States*, 402 U.S. 146 (1971) (loan sharking); *Katzenbach v. McClung*, 379 U.S. 294 (1964), and *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 294 (1964) (restaurants and hotels); *Wickard*, 317 U.S. 111 (commercial farming).

In contrast, each time this Court has faced the question of whether to sustain federal regulation of noneconomic intrastate activities based on their purported aggregate effect on commerce, it has declined to do so. In *Lopez*, the Court invalidated the Gun-Free School Zones Act, which made possession of a firearm in a school zone a federal crime. "[C]entral" to this Court's decision to strike down the statute was the "noneconomic, criminal nature of the conduct at issue." *Morrison*, 529 U.S. at 610; *see also Lopez*, 514 U.S. at 561 (distinguishing gun possession law from "our cases upholding regulations of *activities that arise out of or are connected with a commercial transaction*, which viewed in the aggregate, substantially affects commerce") (emphasis added); *id.* at 580 (Kennedy, J., concurring) (Gun-Free School Zones Act did not involve "actors [or] conduct" that had "a commercial character"). Similarly, a key factor in *Morrison* that led to invalidation of the Violence Against Women Act's (VAWA) civil remedy was that the conduct at issue – "[g]ender-motivated crimes of violence" – was not, "in any sense of the phrase, economic activity." 529 U.S. at 613. *See also Jones v. United States*, 529 U.S. 848, 858 (2000) (interpreting federal arson statute "to avoid the constitutional question that would arise" if the statute covered owner-occupied dwellings).

Here, the conduct at issue is not of a "commercial character" or part of a larger "economic endeavor." Respondents do not sell, barter, or exchange the cannabis. They do not use cannabis as an input for any other product or service that they sell, barter, or exchange. They do not

cultivate cannabis as part of a business (such as hotels and restaurants) with an explicit connection to interstate commerce. Respondent Diane Monson grows and uses cannabis on her doctor's recommendation because her chronic back pain and spasms "cannot be relieved in any other way" and because prescription pharmaceutical medications "always" interfere with her ability to function. J.A. 58. She grows only enough cannabis to meet her own personal medical needs and cultivates it in her yard, using only local materials. J.A. 59; Pet. App. 6a. (federal agents seized six cannabis plants). Respondent Angel Raich, faced with dire, life-threatening medical conditions and severe allergies that prevent her from using conventional drugs, does the same, except that she relies on her caregivers to tend her plants for her because she is unable to do so by herself. Raich's caregivers tend her plants as an act of compassion. They do not receive payment or any item of economic value for their efforts. These limited activities, expressly authorized by State law and undertaken to avoid severe pain or even death, are simply "beyond the realm of commerce in the ordinary and usual sense of that term." *Lopez*, 514 U.S. at 583 (Kennedy, J., concurring).

Petitioners forthrightly concede that Respondents' activities are "not commercial in the sense of involving a transaction for consideration." Pet. Br. 39. They assert, however, that Respondents' activities are "economic," "to at least the same extent as Roscoe Filburn's home-grown production of wheat in *Wickard*" because Respondents "are producing a fungible commodity for which there is an established market." Pet. Br. 37. As explained *supra* pp. 14-18, this argument goes well beyond the facts and holding of *Wickard*. Petitioners' argument, if accepted, would effectively obliterate the distinction between economic and noneconomic activity recognized in *Lopez* and *Morrison*.

"In a sense any conduct in this interdependent world of ours has an ultimate commercial origin or consequence."

Lopez, 514 U.S. at 580 (Kennedy, J., concurring). Thus, if the distinction between economic and noneconomic activity is to be effective, it must differentiate between intrastate activities that are part of a business endeavor, commercial transaction, or other economic enterprise and those that are not. A homeowner planting and tending roses in his or her backyard, for example, is readily distinguished from a nursery owner cultivating roses as part of a commercial operation. Similarly, a parent taking care of his or her own child is easily distinguished from a daycare center providing the same service for a fee. If Petitioners' definition of "economic activity" were accepted, the backyard gardener would be engaged in "economic activity," because there is "an established market" for roses, and homeowners could substitute purchased roses for home-grown roses. So would the parent, because there is an "established market" for child care, and parents could substitute purchased child care for do-it-yourself child care. *Compare Morrison*, 529 U.S. at 615-16 (rejecting an interpretation of the Commerce Clause that would permit federal regulation of "family law" even though "the aggregate effect of . . . childrearing on the national economy is undoubtedly significant"). Given the vast array of goods and services readily available in today's marketplace, no area of human activity would fall outside the realm of economic activity as defined by Petitioners.

In *Lopez* and *Morrison*, this Court rejected arguments by the Federal Government that would effectively eliminate "judicially enforceable outer limits" to the Commerce Power. *See Lopez*, 514 U.S. at 565-66; *Morrison*, 529 U.S. at 615-17. It should do so here as well. Thus far, this Court has had little difficulty charting a sensible division between commercial and noncommercial intrastate activity. While this distinction "may *in some cases* result in legal uncertainty," *Lopez*, 514 U.S. at 566 (emphasis added), there is no uncertainty in this case. The non-commercial, noneconomic character of Respondents' activity, like that of

the gardener and parent, is evident. Wherever the line between economic and noneconomic activity is drawn, Respondents' activities fall well on the noneconomic side.[15]

2. The CSA lacks a jurisdictional element.

It is undisputed that the CSA, like the laws in *Lopez* and *Morrison*, lacks any "jurisdictional element that would lend support to the argument that [it] is sufficiently tied to interstate commerce." *Morrison*, 529 U.S. at 613 (internal citation omitted); *see also Lopez*, 514 U.S. at 561-62 (jurisdictional element could "ensure, through case-by-case inquiry, that the [activity] in question affects interstate commerce"). Indeed, the CSA does not require a showing of any effect on commerce, let alone interstate commerce.

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[15] Petitioners seek to bolster their argument by invoking the Necessary and Proper Clause. The Federal Government also invoked this Clause without success in *Lopez* and *Morrison*. The economic/noneconomic distinction employed in *Lopez* and *Morrison* can be understood as a judicially administrable means of effectuating the Necessary and Proper Clause. *See* J. Randy Beck, *The New Jurisprudence of the Necessary and Proper Clause*, 2002 U. Ill. L. Rev. 581, 625 (2002) ("[L]imiting Congress to the regulation of *economic* activity ensures that such regulations will, in most circumstances, be plainly adopted and really calculated to achieve some legitimate end connected with the interstate economy."). By allowing Congress to go beyond the regulation of interstate commerce itself to reach intrastate economic activity that "substantially affects" commerce, and by also allowing Congress to aggregate the effects of intrastate economic activity to demonstrate their substantial effect on interstate commerce, the Court has already stretched the Commerce Power as far (or farther) than is warranted by the Necessary and Proper Clause. Allowing Congress to reach the class of activity identified in this case would violate the Necessary and Proper Clause by enabling Congress improperly to exercise its power over interstate commerce.

3. Congress' findings do not support the conclusion that Respondents' activities substantially affect interstate commerce.

"[T]he existence of congressional findings is not sufficient, by itself, to sustain the constitutionality of Commerce Clause legislation." *Morrison*, 529 U.S. at 614. "[W]hether particular operations affect interstate commerce sufficiently to come under the constitutional power of Congress to regulate them is ultimately a judicial rather than a legislative question." *Id.* (quoting *Lopez*, 514 U.S. at 557 n.2). Here, the CSA's legislative findings do not support applying the statute to Respondents. *First*, the findings are extremely general, purporting to address all manufacture, distribution, and possession of all controlled substances. Congress made no finding that medical use of locally-grown cannabis, when recommended by a physician and authorized by State law, has a substantial effect on interstate commerce. *Second*, in sharp contrast to other cases in which this Court has accepted congressional findings, there is no legislative record to support the conclusion that allowing medical use of locally-grown cannabis pursuant to State law substantially affects interstate commerce. To the contrary, the legislative record indicates that Congress did not consider the issue at all.

a) The generalized legislative findings of the CSA are inadequate.

i. Not all controlled substances move in interstate commerce. Congress found that: "(A) after manufacture, *many* controlled substances are transported in interstate commerce," "(B) controlled substances distributed locally *usually* have been transported before their distribution," and "(C) controlled substances *commonly* flow through interstate commerce immediately prior to such possession." 21 U.S.C. § 801(3) (emphasis added). These findings do not even purport to determine whether medical cannabis permitted by

the Compassionate Use Act has a substantial effect on interstate commerce. It is undisputed that the cannabis used by Respondents for medical purposes *does not* move, *is never* transported, and *has never* flowed through interstate commerce. Congress implicitly recognized that *some* cannabis falls into this category.

ii. There is no "swelling" of interstate traffic. Petitioners seek to rely on Congress' finding that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances." 21 U.S.C. § 801(4). Petitioners hypothesize a multi-step causal chain: [1] Local possession and cultivation increases the supply of cannabis; [2] an increased supply leads to increased demand; [3] this in turn leads to further increases in supply and marketing. Pet. Br. 24. Petitioners' speculative causal chain cannot withstand analysis.

Petitioners emphasize the vast size of the market for illicit marijuana in the United States. Pet. Br. 19-20 (marijuana is "pervasive[]" in the United States, with a U.S. market totaling $10.5 billion in 2000; "[m]arijuana prices, an indication of marijuana's steady availability, have been stable for years."). In an interstate market of such enormous size, there is no basis for concluding that wholly intrastate activities by a small group of patients involving small quantities of cannabis, subject to State supervision, will have any effect on interstate commerce in marijuana, let alone a substantial effect. By contrast, in *Wickard*, farm-consumed wheat amounted to around 30% of total supply.[16]

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[16] Although there is no evidence that the Compassionate Use Act has any effect on interstate commerce in marijuana, much less a substantial one, it is worth noting that if there were any effect, it would be to decrease rather than "swell" such commerce. By authorizing only local cultivation of cannabis by a patient or the patient's primary caregiver, California law (...continued)

Even apart from the requirements of the California law, medical cannabis patients are less likely than other users to purchase cannabis that has moved in interstate commerce. Patients who use cannabis to prolong their lives or mitigate debilitating pain are far more likely than other users to be concerned about the quality and consistency of the cannabis they consume. *See* J.A. 87, 88 (Raich Decl.) ("[b]lack market marijuana" is an unknown quantity that may contain impurities, and therefore "is just not safe" for medical use). For these reasons, patients who use medical cannabis are more likely than other consumers of marijuana to use only cannabis that they or their caregivers have grown themselves.[17] This factor further distinguishes the class of medical cannabis patients from those who use marijuana recreationally.

iii. The "differentiability" finding is immaterial. Petitioners also seek to rely on the finding that "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate." 21 U.S.C. § 801(5). But so too could it be said that tomatoes grown in a backyard garden cannot be differentiated from those grown on commercial farms and shipped in interstate commerce. Standing alone, this sort of finding cannot constitutionally justify federal prohibition of Respondents' medical cannabis unless there is a basis for concluding that this class of activity somehow increases the flow of interstate marijuana transactions. For this reason, Petitioners are forced to hypothesize (Pet. Br. 25-26) that there is an "appreciable" risk that cannabis cultivated for

discourages purchases of cannabis that has moved illegally in interstate commerce.

[17] Patients may be too ill to cultivate cannabis themselves, but California law accommodates this situation by allowing a patient's primary caregiver to provide assistance.

medical use will be diverted to nonmedical uses. Congress made no such finding with respect to diversion of medical cannabis; Petitioners cite no evidence to support their hypothesis; and there is none in the record. Instead, they simply speculate that patients or their caregivers "may" raise and sell surplus cannabis to raise additional funds (*id.*), even though it is undisputed that Respondents do not engage in such activities. At this point in their argument, as at other crucial points in their brief, Petitioners completely ignore the role of State law and State law enforcement. Diversion is expressly prohibited by California law,[18] and California engages in extensive efforts to enforce its law. *See infra* pp. 36-37. There is no basis for assuming that patients violate State law or that State law enforcement efforts will be so ineffective that any diversion would have a substantial effect on the enormous interstate marijuana market.

iv. Prohibiting Respondents' conduct is not "essential" to control "incidents" of interstate traffic. Finally, Petitioners seek to rely on the finding that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic." 21 U.S.C. § 801(6). In the specific context of medical use of cannabis as authorized by State law, however, there is nothing to support such a finding, and compelling evidence is to the contrary.

The activities at issue in this case have no appreciable impact on the larger scheme of federal law enforcement. The Federal Government rarely brings prosecutions against individuals for possession or cultivation of small amounts of

[18] The Compassionate Use Act states, "Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone diversion of marijuana for nonmedical purposes." Cal. Health & Safety Code § 11362.5(b)(2).

marijuana. The DEA's San Francisco office "target[s] the most significant drug traffickers" – in fact, "[t]he threshold for DEA involvement in marijuana arrests, set by the U.S. attorney, is in the range of 1,000 pounds or 500 plants."[19] In 1999 (the most recent year for which data are publicly available) 38,288 persons whose most serious alleged offense involved a controlled substance were evaluated for federal prosecution by United States Attorneys nationwide. Of these persons, only 471 (1.2%) were evaluated for prosecution for simple possession of marijuana.[20] This pattern of federal prosecution indicates that exempting application of the CSA to medical cannabis patients and caregivers – a small subset of the set of all individuals with small quantities of marijuana – would have virtually no impact on the effectiveness of the federal regulation of controlled substances. The prohibition of Respondents' small-scale personal activities is in no way "essential" to federal "control" over the interstate "incidents" of drug traffic.

b) In contrast to other "substantial effects" cases, the legislative record of the CSA provides scant support for the legislative findings.

The legislative record of the CSA is barren of any indication that Congress considered the situation presented by this case. Petitioners cite no evidence in the hearings on the CSA that would support them, and we are aware of none. This is in sharp contrast to prior cases in which this Court

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[19] Eric Brazil, *Federal Marijuana Law Will Be Enforced Here*, San Francisco Examiner, Nov. 7, 1996, at p. A (reporting statements of Stan Begar, spokesman for the DEA's San Francisco office).

[20] *See* U.S. Dep't of Justice, Office of Justice Programs, Bureau of Justice Statistics, *Special Report: Federal Drug Offenders, 1999 with Trends 1984-99*, at 3 (Aug. 2001), *available at* http://www.ojp.usdoj.gov-/bjs/pub/pdf/fdo99.pdf.

upheld federal legislation against a Commerce Clause challenge, where the legislative record has demonstrated that the activity at issue substantially affects interstate commerce.

In *McClung*, 379 U.S. at 299, for example, Congress held "prolonged hearings" and the "record [was] replete with testimony of the burdens placed on interstate commerce by racial discrimination in restaurants." Similarly, in *Heart of Atlanta Motel*, the Court discussed the "voluminous testimony [that] presents overwhelming evidence that discrimination by hotels and motels impedes interstate travel." 379 U.S. at 253. In *Hodel v. Virginia Surface Mining*, Congress compiled a massive record, "after six years of the most thorough legislative consideration," documenting the ways in which surface coal mining operations harmed interstate commerce. 452 U.S. at 279-80. In *Perez*, 402 U.S. at 155-56, congressional action "grew out of a 'profound study of organized crime, its ramifications, and its implications' undertaken by some 22 Congressmen," a report by the President's Commission on Law Enforcement and Administration of Justice, and an investigation of the loan shark racket undertaken by New York. The record showed that organized crime, which is interstate and international in character, "controlled" the loan shark racket; "through loan sharking the organized underworld has obtained control of legitimate businesses"; and "loan sharking was the second largest source of revenue for organized crime." *Id.* at 155-56 (internal citation omitted).

In sharp contrast, the legislative record of the CSA provides scant support for its conclusory findings, and no support with respect the particular activity at issue in this case. As this Court said in *Lopez*, "'Simply because Congress may conclude that a particular activity substantially affects interstate commerce does not necessarily make it so'". 514 U.S. at 557 n.2 (quoting *Hodel*, 452 U.S. at 311 (Rehnquist, J., concurring)). Moreover, the congressional findings in the CSA are directly at odds with the factual

record in this case. As in *Lopez*, "To uphold the Government's contentions here" would be "*to pile inference upon inference* in a manner that would . . . convert congressional authority under the Commerce Clause to a general police power of the sort retained by the States." 514 U.S. at 567 (emphasis added).

4. The link between Respondents' activities and interstate commerce is "attenuated" at best.

Petitioners try to avoid the now-discredited argument that Respondents' activity is subject to federal regulation because it has "effects on employment, production, transit or consumption," *Morrison*, 529 U.S. at 615, but they still seek to construct and "follow the but-for causal chain" from the initial crime ("the suppression of which has always been the prime object of the States' police power"), through multiple links, to an "attenuated effect upon interstate commerce." *Id.* As explained above, Respondents' activity is non-commercial in nature, and has no effect, substantial or otherwise, on interstate commerce. Petitioners' argument that the activities of California cannabis patients will, in the aggregate, have a substantial effect on interstate commerce depends on unproven speculation that: (1) patients and their caregivers will disobey State law, despite strong incentives not to do so; (2) State law enforcement efforts will be inadequate to prevent such violations; and (3) any such violations will be on such a large scale that they will have a substantial effect on the vast illegal interstate commerce in marijuana. It is far from obvious that any of the links in this attenuated casual chain are valid.

D. Prohibiting Respondents' Activities Is Not Essential To A Larger Regulation Of Interstate Economic Activity.

Petitioners (Pet. Br. 16) seek to rely on a sentence in *Lopez* in which the Court observes that the Gun Free School Zone Act was "not an *essential* part of a larger regulation of

economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561 (emphasis added). Nothing in *Lopez* suggests that, by this single sentence, the Court was providing an escape route by which Congress may expand its powers to reach wholly intrastate *non*economic activity with no substantial effect on interstate commerce. Indeed, the very next sentence in the Court's opinion reaffirmed that the federal statute "cannot, therefore, be sustained under our cases upholding regulations of *activities that arise out of or are connected with a commercial transaction*, which viewed in the aggregate, substantially affects interstate commerce." *Id.* (emphasis added). The sentence relied upon by Petitioners does not dispense with the need to show that the activities "arise out of or are connected with a commercial transaction."[21] Indeed in *Morrison*, the provision at issue

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[21] Likewise, Petitioners twice quote (Pet. Br. 14-15 & 36) the statement in *Lopez* that "where a general regulatory statute bears a substantial relation to commerce, the de minimis character of individual instances arising under that statute is of no consequence." 514 U.S. at 558 (quoting *Maryland v. Wirtz*, 392 U.S. 183, 197, n.27 (1968)). The full quote from *Lopez*, however, reveals the Court's meaning:

> "[T]he *Wirtz* Court replied that . . . "neither here nor in *Wickard* has the Court declared that Congress may use a relatively trivial impact on commerce as an excuse for broad general regulation of state or private activities" . . . . *Rather, "the Court has said only that* where a general regulatory statute bears a substantial relation to commerce, the de minimis character of individual instances arising under that statute is of no consequence."

Lopez, 514 U.S. at 558 (emphasis added and citations and quotations omitted). In context, the Court affirmed that Congress may not reach a class of activities that has only "a relatively trivial impact on commerce *as an excuse* for broad general regulation of state or private activities," *id.* (emphasis added). This language does not allow a generally constitutional regulatory statute, such as the CSA, to be applied to an entire class of activities bearing no relation to interstate commerce.

was not saved by the fact it was part of a larger scheme regulating interstate commerce.

Moreover, as explained above, *see supra* pp. 21, 36, even if one were to assume for the sake of argument that *Lopez* authorizes Congress to reach some noneconomic intrastate activity as part of a broader regulatory scheme, the federal scheme is not "undercut" by medical use of locally-grown cannabis supervised by a physician and State officials, and therefore regulation of such activity is not "essential" to the federal scheme.

Petitioners introduced no evidence in the courts below, and they have represented to this Court that consideration of factual issues is unnecessary. Pet. Reply Br. 4. Yet, in their brief on the merits, Petitioners seek to bolster their argument with unsupported factual assertions. For example, they assert that if the decision below is upheld, "persons operating intrastate could function essentially as unregulated and unsupervised drug manufacturers and pharmacies." Pet. Br. 34. In making such a sweeping assertion, Petitioners completely ignore that activities of Respondents and other patients, and their physicians and caregivers, are, in fact, regulated and supervised by State law and State officials.

Petitioners speculate that there will be widespread violations of California law, but there is no evidence to support this speculation. This Court "presume[s] that [State] law enforcement officers are ready and able to enforce" the law. *Riley v. Nat'l Fed'n of Blind*, 487 U.S. 781, 795 (1988). The evidence indicates that California is doing just that.[22]

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[22] Other States that have enacted Compassionate Use laws appear to be doing the same. *See, e.g., Washington v. Shepherd*, 41 P.3d 1235, 1238-39 (Wash. Ct. App. 2002) (affirming conviction for felony marijuana possession because defendant, who claimed he was a "designated primary caregiver" for patient, did not comply with the Washington Medical Use of Marijuana Act's requirements); KATU News, Medical marijuana (...continued)

See, e.g., Office of the Attorney General, State of California, *Attorney General Lockyer Issues Statement on Federal Threat to Cut State's Share of Anti-Drug Funds* (May 21, 2003), *available at* http://caag.state.ca.us/newsalerts/2003/03-062.htm ("Our CAMP program has continued to break records every year in the amount of marijuana seized. Since 1999, we have seized more than 1.25 million illegal marijuana plants worth more than $4 billion."). In addition, California has directed its Attorney General to "develop and adopt appropriate guidelines to ensure the security and nondiversion of marijuana grown for medical use by patients qualified under the Compassionate Use Act of 1996." Cal. Health & Safety Code § 11362.81.

Petitioners also contend that application of the CSA to Respondents is essential to maintain the "comprehensive" "closed system" of federal regulation of all possession, distribution, and manufacturing of controlled substances. Pet. Br. 32-35. This is simply bootstrapping. If Congress could overcome a Commerce Clause challenge merely by stating that it wished to create a "comprehensive" and "closed" system of federal regulation, it could easily erase the dividing line "between what is truly national and what is truly local." *Morrison*, 529 U.S. at 617-18. The dual sovereignty that comprises the American system of federalism is not a "closed system" and cannot be made so by a federal statute. To create a completely "closed system" of regulation requires a constitutional amendment. *E.g.*, U.S. Const. amend. XVIII.

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leader convicted of drug charges (June 9, 2003), www.katu.com/news/story.asp?ID=58243 (Oregon defendant jailed for possessing 37 cannabis plants and over one pound of dried cannabis at his home, in violation of Oregon medical cannabis law limit of seven plants or seven ounces of dried cannabis).

Finally, Petitioners contend that applying the CSA to persons such as Respondents is essential to avoid intractable problems of proof. *See* Pet. Br. 30 ("difficult, if not impossible, questions of proof" would arise "if the government were required to demonstrate that a given quantity of marijuana . . . had previously entered, or would enter, the stream of monetary commerce"); *id.* at 31 ("It would often be difficult to prove whether relatively small quantities of marijuana were being held, produced, or distributed for commercial, recreational, or medicinal use."). In the instant case, there are no "questions of proof" because the uncontroverted facts in the record are that Respondents' activities are authorized by State law and that there is *no* interstate activity and *no* commerce.[23]

Respondents are raising an as-applied challenge to the CSA; they are not challenging the constitutionality of the CSA on its face. If Respondents prevail, they will not invalidate the CSA. Instead, in future prosecutions, defendants wishing to assert similar as-applied challenges, not the Federal Government, would bear the burden of showing that they possessed or cultivated small quantities of cannabis intrastate solely for personal medical use, in conformity with State law. *See, e.g., Spence v. Washington*, 418 U.S. 405, 409 (1974) (defendant raising as-applied First Amendment challenge must show his activity is entitled to First Amendment protection). Such defendants could meet their burden, in part, on the basis of a State-issued identification card, showing that they are recognized by the State as bona fide medical cannabis patients or caregivers.[24] Defendants could also provide other forms of proof, such as testimony from their physicians. But the burden of proof would be on the defendant, not the Federal Government. *See id.*[25]

II. APPLYING THE CSA TO RESPONDENTS CONTRAVENES CORE PRINCIPLES OF FEDERALISM AND STATE SOVEREIGNTY.

The scope of the Commerce Power "must be considered in light of our dual system of government" and interpreted so as not to "obliterate the distinction between what is national and what is local and create a completely centralized government." *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37 (1937). "Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and

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[23] Petitioners also assert (Pet. Br. 26) that "local illicit drug use for purported medicinal purposes significantly affects ... drug commerce ... by inducing the 'medicinal' user to refrain from consuming lawful drugs ... or by decreasing incentives for research and development into new legitimate drugs." (Internal citation omitted). Once again, Petitioners are speculating without evidence. There is no effective alternative to cannabis for Angel Raich. J.A. 49, 72. The responsible physicians for both Angel Raich and Diane Monson recommended that they use medical cannabis only after they tried conventional medicines and found that they were ineffective, had intolerable side effects, or both. There is no factual basis for concluding that allowing Respondents, and other similarly situated individuals, to use medical cannabis on a physician's recommendation would affect incentives for research and development into new drugs. It is ironic that Petitioners would advance such an argument, because the federal government has placed substantial obstacles in the way of pursuing scientific research involving medical cannabis. *See* Amicus Br. of Rick Doblin, Ph.D., *et al.*

[24] As noted *supra* p. 2 n.2, California has enacted legislation that will allow medical cannabis patients to obtain State-issued identification cards. *See also* App. A, 7a-11a (reproducing relevant statutory provisions).

[25] Even under California law, a defendant must prove that his or her activity is protected under the Compassionate Use Act. *People v. Mower*, 28 Cal. 4th 457, 471, 473 (2002) (Compassionate Use Act provides affirmative defense at trial and allows indictment to be set aside upon affirmative showing by defendant).

the Federal Government will reduce the risk of tyranny and abuse from either front." *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991); *see also New York v. United States*, 505 U.S. 144, 181 (1992) ("Federalism secures to citizens the liberties that derive from the diffusion of sovereign power") (internal quotation and citation omitted); U.S. Const. amend. X.

In both *Lopez* and *Morrison*, the Court took account of principles of federalism and State sovereignty in holding that the federal laws at issue exceeded Congress' Commerce Power. *See Lopez*, 514 U.S. at 564 (rejecting Commerce Clause theories that would extend federal power to areas "where States historically have been sovereign"); *id.* at 567 (Kennedy, J., concurring) ("Were the Federal Government to take over the regulation of entire areas of traditional state concern . . . the boundaries between the spheres of federal and state authority would blur and political responsibility would become illusory."); *Morrison*, 529 U.S. at 618 (VAWA concerned "the police power, which the Founders denied the National Government and reposed in the States"). This case likewise "requires [the Court] . . . to appreciate the significance of federalism in the whole structure of the Constitution." *Lopez*, 514 U.S. at 575 (Kennedy, J., concurring).

"Under our federal system, the 'States possess primary authority for defining and enforcing the criminal law.'" *Lopez*, 514 U.S. at 561 n.3 (quoting *Brecht v. Abrahamson*, 507 U.S. 619, 635 (1993)). In *Lopez*, the Court recognized that there are limits on federal legislative power to criminalize local activity, even "[w]hen Congress criminalizes conduct *already denounced* by the States." 514 U.S. at 561 n.3. (emphasis added). When federal law encroaches on an area traditionally regulated by States, it "effects a 'change in the sensitive relation between federal and state criminal jurisdiction.'" *Id.* (quoting *United States v. Emmons*, 410 U.S. 396, 411-12 (1973)).

In addition to their power to enact local criminal laws, the States possess "broad" powers to regulate "the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977). Indeed, this Court has said that "direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925). California has exercised its police power by enacting the Compassionate Use Act, and other States have followed a similar path. *See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social experiments without risk to the rest of the country.").

As Justice Kennedy has explained, even where the Federal Government and the States share a common goal, such as gun-free schools, there is room for disagreement about how to achieve the goal. "In this circumstance, the theory and utility of our federalism are revealed, for the States may perform their role as laboratories for experimentation." *Lopez*, 514 U.S. at 581 (Kennedy, J., concurring). "If a State or municipality determines that harsh criminal penalties are necessary and wise, . . . the reserved powers of the States are sufficient to enact those measures." *Id.* In *Lopez*, this Court invalidated a federal law that "foreclose[d] the States from experimenting and exercising their own judgment in an area to which States lay claim by right of history and expertise, . . .by regulating an activity beyond the realm of commerce in the ordinary and usual sense of that term." "Absent a stronger connection or identification with commercial concerns that are central to the Commerce Clause, that interference contradicts the federal balance the Framers designed and that this Court is obliged to enforce." *Id.* at 583.

This case presents a more direct and serious interference with State sovereignty than either *Lopez* or *Morrison*. This is

not a situation in which all States agree with the substantive policy goals to be achieved (gun-free schools or an end to violence against women) leaving room for disagreement only as to the appropriate means to achieve those goals. Nor is this a situation in which a State's law is merely silent. Instead, California has adopted a substantive policy – medical use of cannabis in limited circumstances – that is incompatible with application of the CSA to Respondents. The clash between State and federal sovereignty therefore is starker here than it was in either *Lopez* or *Morrison*.[26]

III. THE CSA SHOULD NOT BE INTERPRETED TO APPLY TO ACTIVITY AUTHORIZED AND SUPERVISED BY STATE LAW.

Where principles of federalism and State sovereignty are directly implicated, as they are in this case, this Court has interpreted federal statutes – even statutes framed in broad terms – so as not to reach activity clearly authorized by the States. In *Parker v. Brown*, 317 U.S. 341 (1943), for example, the Court held that the Sherman Act (which by its terms applies to "every contract, combination . . . , or conspiracy in restraint of trade or commerce among the several States," 15 U.S.C. § 1) should not be interpreted to

[26] The decision below is also supported by the principles of State sovereignty that provide "external limits" on the Commerce Power. *See* Kathleen M. Sullivan & Gerald Gunther, *Constitutional Law* 178-79 (15th ed. 2004). By directly obstructing the State's exercise of its broad police power to protect the health, safety, and welfare of its citizens – a power that Congress lacks – the Federal Government exceeds the external limits on its Commerce Power every bit as much as if it had directly commandeered an aspect of State government. *See Conant*, 309 F.3d at 645-47 (Kozinski, J., concurring). Therefore the CSA, if interpreted to apply to wholly intrastate activity expressly authorized and supervised by a State in the constitutional exercise of its police power, would be an "improper" and unconstitutional exercise of the Commerce Power.

apply to actions by one of the States.[27] The Court based its holding squarely on principles of federalism. "In a dual system of government," the Court said, "in which, under the Constitution, the states are sovereign, save only as Congress may constitutionally subtract from their authority, an unexpected purpose to nullify a state's control over its officers and agents is not lightly to be attributed to Congress." 317 U.S. at 351. *See also City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 370 (1991) (*Parker* rests on "principles of federalism and state sovereignty"). The Court noted that "[t]he Sherman Act makes no mention of the state as such, and gives no hint that it was intended to restrain state action." 317 U.S. at 351. Similarly, "[t]here is no suggestion of a purpose to restrain state action in the Act's legislative history." *Id.* Accordingly, the Court held, where "[t]he state itself exercises its legislative authority in making the regulation and in prescribing the conditions of its application," the Court would assume that Congress did not intend the Sherman Act, despite its general language, to apply. This "State action doctrine" is not limited to acts of a State and its officials, but extends to private actions that otherwise would violate federal law, so long as (i) those actions are authorized by State law pursuant to a "clearly articulated and affirmatively expressed state policy," and (ii) the policy is "actively supervised" by the State. *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980).

[27] Consideration of the *Parker* State action doctrine, although not directly raised below, is required by the "cardinal principle" that before addressing constitutional issues "this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided." *Ashwander v. TVA*, 297 U.S. 288, 348-49 (1936). *See also Thigpen v. Roberts*, 468 U.S. 27, 29-30 (1984) (Court "may affirm on any ground that the law and the record permit").

The principles of federalism and State sovereignty that underlie the State action doctrine of *Parker v. Brown* apply in this case as well. Here, as in *Parker*, the Court is reviewing a broadly-worded criminal statute. As in *Parker*, there is no indication in the text or legislative history that Congress intended to prohibit State action. As in *Parker*, a State law clearly authorizes the activity in question, and State officials both "have and exercise power to review particular . . . acts of private parties and disapprove those that fail to accord with state policy." *Patrick v. Burget*, 486 U.S. 94, 101 (1988). California law permits patients to use medical cannabis only upon the recommendation of a State-licensed physician and only subject to supervision by State law enforcement officers. The principles of federalism and State sovereignty that guided this Court's decision in *Parker* lead to the conclusion that the CSA, like the Sherman Act, should not be interpreted to prohibit conduct clearly authorized and actively supervised by a State in the exercise of its sovereign police powers.

Additional support for interpreting the CSA in this manner comes from *Gregory v. Ashcroft*, 501 U.S. 452 (1991), where this Court held that a State-enacted mandatory retirement age for State judges did not violate the Age Discrimination in Employment Act, 29 U.S.C. §§ 621-634. The Court reached this result by applying a "plain statement" requirement, reasoning that "Congress should make its intention 'clear and manifest' if it intends to pre-empt the historic powers of the States." *Id.* at 461 (internal citations omitted).

The CSA does not satisfy the "plain statement" requirement. The CSA defines a "practitioner" as "a physician . . . licensed, registered, or otherwise permitted, by the United States *or the jurisdiction in which he practices* . . ., to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. § 802(21) (emphasis added). The CSA also provides that it

is "unlawful for a person knowingly or intentionally to possess a controlled substance *unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice.*" 21 U.S.C. § 844(a) (emphasis added). Because this language appears to authorize patients to possess medical cannabis pursuant to a State-licensed physician's valid order, the CSA does not state a "clear and manifest" intention to divest the States of their historic police powers to protect the lives and health of citizens. Accordingly, principles of federalism and State sovereignty – which are entitled to decisive weight if the Court decides the Commerce Clause issue – also support interpreting the CSA in a way that avoids that issue. *See Jones v. United States*, 529 U.S. 848 (2000) (interpreting federal arson statute to avoid Commerce Clause issue). *See also* 21 U.S.C. § 903 (CSA should not be construed to "exclude any state law . . . unless there is a positive conflict" such that Federal and State law "cannot consistently stand together").

IV. THERE ARE ADDITIONAL GROUNDS FOR AFFIRMING THE PRELIMINARY INJUNCTION.

A prevailing party may defend the decision of the lower court "on any ground properly raised below." *Washington v. Yakima Indian Nation*, 439 U.S. 463, 478 n.20 (1979); *see also Thigpen v. Roberts*, 468 U.S. 27 (1984). In this case, the court of appeals has decided only that it is appropriate to enter a preliminary injunction pending a final decision on the merits. Under the governing standard, a preliminary injunction is warranted where the balance of hardships tips sharply in favor of the moving party and there are "serious questions going to the merits." *First Brands Corp. v. Fred Meyer, Inc.*, 809 F.2d 1378, 1381 (9th Cir. 1987). Both courts below found that that hardship and public interest factors tip sharply in Respondents' favor, Pet. App. 24a, 68a, and Petitioners do not challenge those findings in this Court. Thus, Respondents are entitled to prevail if a majority of the

Members of this Court conclude that there are serious questions going to the merits. In addition to the issues discussed above, Respondents have asserted two other grounds for relief, each of which raises a serious question going to the merits.[28]

A. This Case Presents The "Difficult Issue" Of Whether The Doctrine Of Necessity Protects Respondents.

This Court will avoid decision of serious constitutional issues when it is fairly possible to do so. *See Jones v. United States*, 529 U.S. 848, 857 (2000) (construing federal statute to avoid a "grave and doubtful constitutional questions" under the Commerce Clause); *Ashwander v. TVA*, 297 U.S. 288, 345-48 (1936) (Brandeis, J., concurring). In the courts below, Respondents raised a claim based on the non-constitutional doctrine of medical necessity. In *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001) ("*OCBC*"), a case involving a medical cannabis cooperative, this Court held that "medical necessity is not a defense to *manufacturing and distributing* marijuana.") *Id.* at 494 (emphasis added). In a separate opinion, Justice Stevens, joined by Justices Souter and Ginsburg, emphasized that "whether the defense might be available to a seriously ill patient for whom there is no alternative means of avoiding starvation or extraordinary suffering is a difficult issue that [was] not presented" in *OCBC*. *Id.* at 501. This case

[28] If a majority of the Members of this Court conclude that Respondents have raised a serious question going to the merits, the preliminary injunction should remain in effect, even if a majority do not agree on which particular issue raises the serious question. *See, e.g., Eastern Enters. v. Apfel*, 524 U.S. 498, 537, 550 (1998) (resting judgment on multiple grounds); *Welsh v. United States*, 398 U.S. 333, 335, 345 (1970) (same); *Nat'l Mut. Ins. Co. v. Tidewater Transfer Co.*, 337 U.S. 582 (1949) (same).

presents precisely that "difficult issue." The undisputed record evidence shows that Angel Raich is seriously ill, and she has no alternative means of avoiding starvation or extraordinary suffering.[29]

The doctrine of necessity "traditionally covered the situation where physical forces beyond the actor's control rendered illegal conduct the lesser of two evils" and the actor had no "reasonable, legal alternative to violating the law." *United States v. Bailey*, 444 U.S. 394, 410 (1980). In *Bailey*, no Member of the Court doubted "the existence of such a defense," even though the statute at issue did not mention necessity. *Id.* at 415 n.11.

In *OCBC*, the Court held that the necessity doctrine does not apply when invoked by persons who are not *themselves* facing physical harm. 532 U.S. at 486-87, 494. In *OCBC*, unlike this case, no patient was a party to the litigation. The cooperative and its executive director had not "been forced to confront a choice of evils." *Id.* at 500 n.1 (Stevens, J., concurring in the judgment). Instead, they had "thrust that choice upon themselves by *electing* to become distributors for [seriously ill] patients." *Id.* (emphasis added).

In this case, in contrast, Raich's physician has determined that she "*cannot* be without cannabis as medicine" because she would "quickly" suffer "precipitous medical deterioration" and "could very well" die. J.A. at 48, 51 (emphasis added). Diane Monson's physician has

[29] The Court's opinion in *OCBC* states in a footnote that "nothing in our analysis suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act." 532 U.S. at 494 n.7. As the concurring Justices noted, however, that statement is clearly dictum, and the medical necessity question presented by this case as a "difficult" one. *Id.* at 501 (opinion of Stevens, J.). In *OCBC*, the Court did not encounter individual patients facing severe pain, starvation, and death.

determined that only cannabis will relieve her symptoms. J.A. at 53. In these circumstances, the doctrine of necessity precludes enforcement of the CSA against Respondents.

B. This Case Raises Serious Questions Involving Due Process, Basic Concepts Of Liberty, And Fundamental Rights.

The Fifth Amendment's Due Process Clause precludes the Federal Government from applying the CSA to Respondents' activities. This Court has held "[i]n a long line of cases" that the Due Process Clause protects basic rights and liberties not specifically enumerated in the Constitution. *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997). *See also Planned Parenthood of S.E. Pa. v. Casey*, 505 U.S. 833, 848 (1992) ("Neither the Bill of Rights nor the specific practices of States at the time of the adoption of the Fourteenth Amendment mark the outer limits of the substantive sphere of liberty which the Fourteenth Amendment protects. *See* U.S. Const., Amdt. 9.").

This case involves a right that *is* enumerated in the Due Process Clause – the right to life itself. *See* J.A. 51 ("It could very well be fatal for Angel to forego cannabis treatment."). It also implicates the rights to avoid or mitigate severe pain and protect bodily integrity – rights that at least five Members of this Court have indicated may well be constitutionally protected. *See Glucksberg* 521 U.S. at 736-37 (opinion of O'Connor, J.) ("A patient who is suffering from a terminal illness and who is experiencing great pain" may have a "constitutionally cognizable interest" in "obtaining medication, from qualified physicians, to alleviate that suffering"); *id.* at 789 (opinion of Ginsburg, J.) (agreeing with Justice O'Connor); *id.* at 745 (opinion of Stevens, J.) ("Avoiding intolerable pain and . . . agony is certainly [a]t the heart of [the] liberty . . . to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life."); *id.* at 777 (opinion of Souter, J.) ("liberty

interest in bodily integrity" includes "a right to determine what shall be done with his own body in relation to his medical needs"); *id.* at 790 (opinion of Breyer, J.) (Due Process Clause may protect right to "personal control over the manner of death, professional medical assistance, and the avoidance of unnecessary and severe physical suffering – combined."). Each of these rights has deep roots in "our Nation's history, legal traditions, and practices." *Id.* at 710.[30]

"'History and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry.'" *Lawrence v. Texas*, 123 S. Ct. 2472, 2480 (2003) (quoting *County of Sacramento v. Lewis*, 523 U.S. 833, 857 (1998) (Kennedy, J., concurring)). Current practices – particularly those authorized by an increasing number of States – are also significant. *Lawrence* 123 S. Ct. at 2480. *See* App. B, *infra*. (describing State laws). In *Lawrence*, moreover, this Court did not apply the "fundamental rights" analysis of *Bowers v. Hardwick*, 478 U.S. 186 (1986), or *Glucksberg*. Instead, it protected the "liberty" to engage in the conduct at issue, without ever deeming the liberty in question a "fundamental right." The same type of analysis leads to protection of Respondents. Their decisions to follow physicians' advice are "within the liberty of persons to

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[30] Respondents are asserting the basic rights described in text, rather than a narrow "right to use medical cannabis." But even if the Court were to focus narrowly on the historical treatment of cannabis, there would still be a strong case for affording constitutional protection to Respondents. There is a long history of medical cannabis use in this country, but no such history for the recent claim of federal power to prohibit it. Medical cannabis did not become illegal under federal law until the CSA was enacted in 1970. *See* Richard J. Bonnie & Charles H. Whitebread, *The Forbidden Fruit and the Tree of Knowledge: An Inquiry into the Legal History of American Marijuana Prohibition*, 56 Va. L. Rev. 971, 1010, 1027, 1165 (1970).

choose without being punished as criminals." *Lawrence*, 123 S. Ct. at 2478.

The Federal Government has no compelling interest in condemning Angel Raich and Diane Monson to avoidable suffering and even death.[31] To the contrary, the Federal Government "has an important interest" in enabling "patients with particular needs" that cannot be addressed with mass-produced conventional medications to use "medications suited to those needs." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 369 (2002). At stake are some of "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy." *Casey*, 505 U.S. at 851. To deny Raich and Monson the medication recommended by their physicians as necessary to relieve excruciating pain, preserve bodily integrity, and extend their lives is to "demean their existence" and "control their destiny." *Lawrence*, 123 S. Ct. at 2484. Such "suffering is too intimate and personal for the [Federal Government] to insist . . . upon its own vision." *Casey*, 505 U.S. at 852.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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[31] In *United States v. Rutherford*, 442 U.S. 544, 551 (1979), the Court, without deciding any constitutional issue, held that the Food, Drug and Cosmetic Act did not require the FDA to permit laetrile to be *marketed in commerce* to terminally-ill cancer patients. In this case, unlike in *Rutherford*, Respondents are not seeking to compel the federal government, or any of its agencies, to authorize the marketing of cannabis, or to take any other affirmative action. Instead, Respondents are seeking the right to be left alone so that patients may follow their physicians' recommendations by using a medication they or their caregivers produce for themselves. This case also differs from *Rutherford* in that no peer-reviewed medical study had ever found that laetrile has medical benefits. *Cf. supra* pp. 2-3 (describing medical evidence concerning cannabis).

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APPENDIX A

FEDERAL CONSTITUTIONAL PROVISIONS INVOLVED

The Commerce Clause of the United States Constitution provides that "The Congress shall have Power … To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."

The Fifth Amendment of the United States Constitution provides that "No person …shall be …deprived of life, liberty, or property, without due process of law."

The Ninth Amendment of the United States Constitution provides that "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."

The Tenth Amendment of the United States Constitution provides that "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

SELECTED PROVISIONS OF THE CONTROLLED SUBSTANCES ACT
(21 U.S.C. § 801 *et seq.*)

§ 802. Definitions

* * *

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a

controlled substance to an ultimate user or research subject.

* * *

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

* * *

§ 844. Penalty for Simple Possession

(a) Unlawful acts; penalties. It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this title or title III.

* * *

§ 903. Application of State Law

No provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together.

SELECTED PROVISIONS OF THE CALIFORNIA COMPASSIONATE USE ACT
(Cal. Health & Safety Code § 11362.5 *et seq.*)

§ 11362.5. Medical use

(a) This section shall be known and may be cited as the Compassionate Use Act of 1996.

(b)(1) The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:

(A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

(B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.

(C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana.

(2) Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for nonmedical purposes.

(c) Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or

privilege, for having recommended marijuana to a patient for medical purposes.

(d) Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.

(e) For the purposes of this section, "primary caregiver" means the individual designated by the person exempted under this section who has consistently assumed responsibility for the housing, health, or safety of that person.

§ 11362.7. Definitions

For purposes of this article, the following definitions shall apply:

(a) "Attending physician" means an individual who possesses a license in good standing to practice medicine or osteopathy issued by the Medical Board of California or the Osteopathic Medical Board of California and who has taken responsibility for an aspect of the medical care, treatment, diagnosis, counseling, or referral of a patient and who has conducted a medical examination of that patient before recording in the patient's medical record the physician's assessment of whether the patient has a serious medical condition and whether the medical use of marijuana is appropriate.

(b) "Department" means the State Department of Health Services.

(c) "Person with an identification card" means an individual who is a qualified patient who has applied for and

received a valid identification card pursuant to this article.

(d) "Primary caregiver" means the individual, designated by a qualified patient or by a person with an identification card, who has consistently assumed responsibility for the housing, health, or safety of that patient or person, and may include any of the following:

(1) In any case in which a qualified patient or person with an identification card receives medical care or supportive services, or both, from a clinic licensed pursuant to Chapter 1 (commencing with Section 1200) of Division 2, a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2, a residential care facility for persons with chronic life-threatening illness licensed pursuant to Chapter 3.01 (commencing with Section 1568.01) of Division 2, a residential care facility for the elderly licensed pursuant to Chapter 3.2 (commencing with Section 1569) of Division 2, a hospice, or a home health agency licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2, the owner or operator, or no more than three employees who are designated by the owner or operator, of the clinic, facility, hospice, or home health agency, if designated as a primary caregiver by that qualified patient or person with an identification card.

(2) An individual who has been designated as a primary caregiver by more than one qualified patient or person with an identification card, if every qualified patient or person with an identification card who has designated that individual as a primary caregiver resides in the same city or county as the primary caregiver.

(3) An individual who has been designated as a primary caregiver by a qualified patient or person with an identification card who resides in a city or county

other than that of the primary caregiver, if the individual has not been designated as a primary caregiver by any other qualified patient or person with an identification card.

(e) A primary caregiver shall be at least 18 years of age, unless the primary caregiver is the parent of a minor child who is a qualified patient or a person with an identification card or the primary caregiver is a person otherwise entitled to make medical decisions under state law pursuant to Sections 6922, 7002, 7050, or 7120 of the Family Code.

(f) "Qualified patient" means a person who is entitled to the protections of Section 11362.5, but who does not have an identification card issued pursuant to this article.

(g) "Identification card" means a document issued by the State Department of Health Services that document identifies a person authorized to engage in the medical use of marijuana and the person's designated primary caregiver, if any.

(h) "Serious medical condition" means all of the following medical conditions:

(1) Acquired immune deficiency syndrome (AIDS).
(2) Anorexia.
(3) Arthritis.
(4) Cachexia.
(5) Cancer.
(6) Chronic pain.
(7) Glaucoma.
(8) Migraine.
(9) Persistent muscle spasms, including, but not limited to, spasms associated with multiple sclerosis.
(10) Seizures, including, but not limited to, seizures associated with epilepsy.
(11) Severe nausea.

(12) Any other chronic or persistent medical symptom that either:
(A) Substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans with Disabilities Act of 1990 (Public Law 101-336).
(B) If not alleviated, may cause serious harm to the patient's safety or physical or mental health.

(i) "Written documentation" means accurate reproductions of those portions of a patient's medical records that have been created by the attending physician, that contain the information required by paragraph (2) of subdivision (a) of Section 11362.715, and that the patient may submit to a county health department or the county's designee as part of an application for an identification card.

§ 11362.71. Establishment and maintenance of voluntary program for issuance of identification cards to qualified patients; access to necessary information; duties of county health departments; arrests for possession, transportation, delivery or cultivation

(a)(1) The department shall establish and maintain a voluntary program for the issuance of identification cards to qualified patients who satisfy the requirements of this article and voluntarily apply to the identification card program.

(2) The department shall establish and maintain a 24-hour, toll-free telephone number that will enable state and local law enforcement officers to have immediate access to information necessary to verify the validity of an identification card issued by the department, until a cost-effective Internet Web-based system can be developed for this purpose.

(b) Every county health department, or the county's designee, shall do all of the following:

(1) Provide applications upon request to individuals seeking to join the identification card program.

(2) Receive and process completed applications in accordance with Section 11362.72.

(3) Maintain records of identification card programs.

(4) Utilize protocols developed by the department pursuant to paragraph (1) of subdivision (d).

(5) Issue identification cards developed by the department to approved applicants and designated primary caregivers.

(c) The county board of supervisors may designate another health-related governmental or nongovernmental entity or organization to perform the functions described in subdivision (b), except for an entity or organization that cultivates or distributes marijuana.

(d) The department shall develop all of the following:

(1) Protocols that shall be used by a county health department or the county's designee to implement the responsibilities described in subdivision (b), including, but not limited to, protocols to confirm the accuracy of information contained in an application and to protect the confidentiality of program records.

(2) Application forms that shall be issued to requesting applicants.

(3) An identification card that identifies a person authorized to engage in the medical use of marijuana and an identification card that identifies the person's designated primary caregiver, if any. The two identification cards developed pursuant to this paragraph shall be easily distinguishable from each other.

(e) No person or designated primary caregiver in possession of a valid identification card shall be subject to arrest for possession, transportation, delivery, or cultivation of medical marijuana in an amount established pursuant to this article, unless there is reasonable cause to believe that the information contained in the card is false or falsified, the card has been obtained by means of fraud, or the person is otherwise in violation of the provisions of this article.

(f) It shall not be necessary for a person to obtain an identification card in order to claim the protections of Section 11362.5.

§ 11362.72. Duties of county health department or county's designee after receipt of application for identification card; approval of application; issuance of card

(a) Within 30 days of receipt of an application for an identification card, a county health department or the county's designee shall do all of the following:

(1) For purposes of processing the application, verify that the information contained in the application is accurate. If the person is less than 18 years of age, the county health department or its designee shall also contact the parent with legal authority to make medical decisions, legal guardian, or other person or entity with legal authority to make medical decisions, to verify the information.

(2) Verify with the Medical Board of California or the Osteopathic Medical Board of California that the attending physician has a license in good standing to practice medicine or osteopathy in the state.

(3) Contact the attending physician by facsimile, telephone, or mail to confirm that the medical records

submitted by the patient are a true and correct copy of those contained in the physician's office records. When contacted by a county health department or the county's designee, the attending physician shall confirm or deny that the contents of the medical records are accurate.

(4) Take a photograph or otherwise obtain an electronically transmissible image of the applicant and of the designated primary caregiver, if any.

(5) Approve or deny the application. If an applicant who meets the requirements of Section 11362.715 can establish that an identification card is needed on an emergency basis, the county or its designee shall issue a temporary identification card that shall be valid for 30 days from the date of issuance. The county, or its designee, may extend the temporary identification card for no more than 30 days at a time, so long as the applicant continues to meet the requirements of this paragraph.

(b) If the county health department or the county's designee approves the application, it shall, within 24 hours, or by the end of the next working day of approving the application, electronically transmit the following information to the department:

(1) A unique user identification number of the applicant.

(2) The date of expiration of the identification card.

(3) The name and telephone number of the county health department or the county's designee that has approved the application.

(c) The county health department or the county's designee shall issue an identification card to the applicant and to his or her designated primary caregiver, if any, within five working days of approving the application.

(d) In any case involving an incomplete application, the applicant shall assume responsibility for rectifying the deficiency. The county shall have 14 days from the receipt of information from the applicant pursuant to this subdivision to approve or deny the application.

§ 11362.735. Serially numbered identification cards; contents; copy given to primary caregiver

(a) An identification card issued by the county health department shall be serially numbered and shall contain all of the following:

(1) A unique user identification number of the cardholder.

(2) The date of expiration of the identification card.

(3) The name and telephone number of the county health department or the county's designee that has approved the application.

(4) A 24-hour, toll-free telephone number, to be maintained by the department, that will enable state and local law enforcement officers to have immediate access to information necessary to verify the validity of the card.

(5) Photo identification of the cardholder.

(b) A separate identification card shall be issued to the person's designated primary caregiver, if any, and shall include a photo identification of the caregiver.

§ 11362.79. Places where medical use of marijuana is prohibited

Nothing in this article shall authorize a qualified patient or person with an identification card to engage in the smoking of medical marijuana under any of the following circumstances:

(a) In any place where smoking is prohibited by law.

(b) In or within 1,000 feet of the grounds of a school, recreation center, or youth center, unless the medical use occurs within a residence.
(c) On a schoolbus.
(d) While in a motor vehicle that is being operated.
(e) While operating a boat.

§ 11362.81. Penalties; application of section; development and adoption of guidelines to ensure security and nondiversion of marijuana grown for medical use

(a) A person specified in subdivision (b) shall be subject to the following penalties:

(1) For the first offense, imprisonment in the county jail for no more than six months or a fine not to exceed one thousand dollars ($1,000), or both.

(2) For a second or subsequent offense, imprisonment in the county jail for no more than one year, or a fine not to exceed one thousand dollars ($1,000), or both.

(b) Subdivision (a) applies to any of the following:

(1) A person who fraudulently represents a medical condition or fraudulently provides any material misinformation to a physician, county health department or the county's designee, or state or local law enforcement agency or officer, for the purpose of falsely obtaining an identification card.

(2) A person who steals or fraudulently uses any person's identification card in order to acquire, possess, cultivate, transport, use, produce, or distribute marijuana.

(3) A person who counterfeits, tampers with, or fraudulently produces an identification card.

(4) A person who breaches the confidentiality requirements of this article to information provided to,

or contained in the records of, the department or of a county health department or the county's designee pertaining to an identification card program.

(c) In addition to the penalties prescribed in subdivision (a), any person described in subdivision (b) may be precluded from attempting to obtain, or obtaining or using, an identification card for a period of up to six months at the discretion of the court.

(d) In addition to the requirements of this article, the Attorney General shall develop and adopt appropriate guidelines to ensure the security and nondiversion of marijuana grown for medical use by patients qualified under the Compassionate Use Act of 1996.

APPENDIX B

STATE LAWS REGARDING MEDICAL CANNABIS

A total of 26 States have recognized the medical benefits of cannabis in some form:

(1) Nine States have enacted laws allowing medical use of cannabis. *See* Alaska Stat. §§ 11.71.090, 17.37.010 (2004) (Michie 2004); Cal. Health & Safety Code § 11362.5 (West 2004); Colo. Rev. Stat. Const. Art. 18, § 4 (2003); Haw. Rev. Stat. Ann. § 329-121 (2004) (Michie 2004); Me. Rev. Stat. Ann. tit. 22, § 2383-B (West 2004); Nev. Rev. Stat. Ann. § 453A.200 (Michie 2004); Or. Rev. Stat. §§ 475.300-.346 (2004); Vt. Stat. Ann. tit. 18 § 4272 (2004); Wash. Rev. Code Ann. §§ 69.51.010-.080 (West 2004).

(2) Five additional States have enacted laws recognizing the therapeutic benefits of cannabis but authorizing use only by prescription, *see* Ariz. Rev. Stat. § 13-3412.01 (West 2004); La. Rev. Stat. Ann. § 40:1201 (West 2004); N.H. Rev. Stat. Ann. § 318-B:10(VI) (2004); Va. Code Ann. § 18.2-251.1 (Michie 2004), or classifying cannabis as having "currently accepted medical uses," *see* Iowa Code §§ 124.205, 124.206(7)(a) (West 2004).

(3) Two additional States have passed resolutions urging the federal government to allow the medical use of cannabis. *See* Mo. Sen. Con. Res. 14 (1994); New Mexicans for Compassionate Use, N.M. Senate Memorial 42 (1982), *available at* http://www.sumeria.net/nmcu/memorial.html.

(4) Seven additional States have enacted laws recognizing cannabis's potential medical benefits for persons suffering from conditions including cancer, nausea, and glaucoma, and establishing therapeutic research programs for the benefit of such persons. *See* Ala. Code § 20-2-111 (2004); Ga. Code Ann. §§ 43-34-120 (2004); 720 Ill. Comp. Stat. 550/11 (2004); Mass. Gen. Law ch. 94D, §§ 1-3 (2004); N.Y. Pub. Health Law §§ 3328(4) 3397-a to 3397-f (McKinney 2004);

Minn. Stat. § 152.21 (2004); S.C. Code Ann. §§ 44-53-620 (Law. Co-op. 2004).

(5) The courts of two additional States have allowed cannabis patients to raise a necessity defense to charges of marijuana possession. *See Sowell v. State*, 738 So.2d 333, 334 (Fla. Dist. Ct. App. 1998); *State v. Hastings*, 801 P.2d 563, 565 (Idaho 1990). A third State recently limited the penalty for possessing cannabis for medical purposes to a $100 fine. *See* Md. Code Crim. Law § 5-601(c)(3) (2004).

This State legislation reflects strong popular support for medical use of cannabis in appropriate circumstances. *See, e.g.*, The Polling Report, Inc., Illegal Drugs, available at http://www.pollingreport.com/drugs.htm (last visited Oct. 10, 2004) (CNN/Time poll) 80 percent of Americans favor allowing adults to use cannabis for medical purposes on a physician's recommendation).

(25)

No. 03-1454

In the Supreme Court of the United States

JOHN D. ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

ANGEL MCCLARY RAICH, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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REPLY BRIEF FOR THE PETITIONERS

Respondents manufacture, distribution, and possession of marijuana involve a fungible commodity that is regularly bought and sold in an interstate market. That market, like the market for numerous other drugs having a significant potential for abuse and dependence, is comprehensively regulated by the Controlled Substances Act (CSA). U.S. Br. 17-20. Schedule I drugs like marijuana, heroin, and LSD have been found to have "no currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(1)(B). In order to eradicate the market for such drugs, the CSA makes it unlawful to manufacture, distribute, dispense, or possess *any* Schedule I drug for *any* purpose, medical or otherwise, except as part of a strictly controlled research project. 21 U.S.C. 823, 841, 844; U.S. Br. 2-3.

Respondents do not challenge the constitutionality of the CSA on its face or, apparently, in most of its applications. Nor do they challenge the status of marijuana as a controlled substance under the CSA or its placement in Schedule I. They nevertheless contend that their own drug-related

activities are beyond the reach of Congress's power under the Commerce Clause. While respondents purport to make only a narrow "as applied" challenge to the CSA, the arguments they advance are not readily cabined. And those arguments are, in any event, without merit.

Respondents contend that their production (i.e., cultivation), distribution, and resulting possession of marijuana are beyond the reach of the Commerce Clause because they engage in that conduct for a medical purpose, based on the recommendation or advice of a physician, consistent with state law. There is, however, no basis in the Commerce Clause for respondents' attempt to distinguish the production, distribution, and possession of marijuana for medical rather than recreational purposes. Under the CSA, moreover, the possible medical use of a controlled substance and the recommendation of a physician (in the form of a prescription) are relevant—indeed central—to how that substance is regulated, but not to *whether* it is regulated. The CSA regulates potentially addictive drugs, whether or not they have medical uses. U.S. Br. 39-43. It therefore would be fundamentally inconsistent with the very premises and regulatory framework of the CSA to exempt respondents from that Act because they assert a medical purpose for their drug activities.

Respondents' argument, moreover, is not logically confined to marijuana. It extends to heroin, LSD, or other Schedule I substances, and would appear to allow them to engage in similar intrastate manufacture, distribution, and possession of drugs on Schedules II through V for "personal medical purposes," without complying with the strict controls the CSA imposes for medical uses.

Nor is it relevant that respondents' conduct may be lawful under state law. Under the Supremacy Clause, state law cannot insulate conduct from the exercise of Congress's enumerated powers. And here, regulation of intrastate ac-

tivities is an essential part of Congress's regulation of the interstate drug market and Congress's goal of achieving a comprehensive and uniform system that guards against drug abuse and diversion and permits manufacturing and distribution for legitimate medical uses only under carefully prescribed safeguards in the CSA itself. U.S. Br. 22-28, 32-35. Absent authority to apply the CSA to local drug activities, the federal government would face enormous impediments to enforcing the CSA's prohibition against drug trafficking and diversion. Illicit drugs such as marijuana are fungible and unlabeled and often provide no clue as to their origin, intended use, or whether they were involved in a cash sale. *Id.* at 28-32.

A. The Drug Activities At Issue Substantially Affect Interstate Commerce

1. Respondents assert that their specific drug-related conduct—the manufacture, distribution, and resulting possession of marijuana for purported medicinal reasons—is intrastate, non-commercial, and "minuscule" in effect, and therefore is wholly beyond the power of Congress to regulate under the Commerce Clause. Br. 16-17, 20, 23-27. Those arguments ignore several fundamental tenets of this Court's jurisprudence.

It has long been established that Congress's power under the Commerce Clause and the Necessary and Proper Clause "extends to those activities intrastate which so affect interstate commerce or the exercise of the power of Congress over it as to make regulation of them appropriate means to the attainment of a legitimate end, the exercise of the granted power of Congress to regulate interstate commerce." *United States* v. *Darby*, 312 U.S. 100, 118 (1941). That power encompasses regulation of the inherently economic activity of producing and distributing a valuable commodity that is sold in an interstate market, see, *e.g.*, *Wickard*

v. *Filburn*, 317 U.S. 111 (1942); *United States* v. *Lopez*, 514 U.S. 549, 560 (1995), as well as possession of the commodity that necessarily results from such production or distribution.

Where "Congress itself has said that a particular activity affects the commerce, * * * the only function of courts is to determine whether the particular activity regulated or prohibited is within the reach of the federal power." *Darby*, 312 U.S. at 120-121. If "that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class." *Perez* v. *United States*, 402 U.S. 146, 154 (1971) (quoting *Maryland* v. *Wirtz*, 392 U.S. 183, 193 (1968)). See *Lopez*, 514 U.S. at 558 (quoted p. 11, *infra*); *id.* at 600 (Thomas, J., concurring).

A court may not avoid this fundamental principle by subdividing the class of activities that Congress defined and focusing narrowly on one subclass that is alleged to have an insufficient nexus to interstate commerce. As long as the class as defined by Congress bears a rational relationship to its regulation of interstate commerce, the statute is constitutional.

In *Wirtz*, *supra*, for example, the Court explained that "*Darby* itself recognized the power of Congress * * * to declare that an entire class of activities affects commerce. The only question for the courts is then whether the class is 'within the reach of the federal power.' The contention that in Commerce Clause cases the courts have power to excise, as trivial, individual instances falling within a *rationally defined class* of activities has been put entirely to rest." 392 U.S. at 192-193 (quoting *Darby*, 312 U.S. at 120-121) (emphasis added). See *Katzenbach* v. *McClung*, 379 U.S. 294, 304 (1964) (sufficient that legislators "have a rational basis for finding a chosen regulatory scheme necessary to the protection of commerce"). Thus, as the Court explained in *Lopez*, the relevant inquiry under its precedents is "whether a rational basis existed for concluding that a regulated

activity sufficiently affected interstate commerce." 514 U.S. at 557.[1]

As explained below and in our opening brief, Congress plainly had a rational basis for including all controlled substances as a class within the statutory scheme and for comprehensively regulating the manufacture, distribution, and resulting possession of such substances, including marijuana, whether those activities occur interstate or intrastate and whether they are pursued for medical or other purposes. Indeed, with the exception of the Ninth Circuit in this case, the courts of appeals that have considered the question have sustained the application of the CSA to similar conduct by concluding that the class of activities is within the reach of Congress's power under the Commerce Clause. See *Proyect* v. *United States*, 101 F.3d 11, 13 (2d Cir. 1996); *United States* v. *Genao*, 79 F.3d 1333, 1336 (2d Cir. 1996); *United States* v. *Leshuk*, 65 F.3d 1105, 1112 (4th Cir. 1995); *United States* v. Scales, 464 F.2d 371, 375-376 (6th Cir. 1972); *United States* v. *Lopez*, 459 F.2d 949, 953 (5th Cir.), cert. denied, 409 U.S. 878 (1972).

2. Respondents' submission is also directly contradicted by *Wickard*, *supra*, which upheld congressional regulation of homegrown wheat even though that activity "may not be regarded as commerce," 317 U.S. at 125, and the wheat was not "sold or intended to be sold," *id.* at 119. The Court reached that result because the production of the wheat was nonetheless economic activity occurring in a regulated market. *Id.* at 128; accord *Lopez*, 514 U.S. at 560-561; U.S. Br. 16.

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[1] Respondents cannot evade this settled precedent simply by emphasizing that their challenge is to the CSA "as applied." The challenges in cases such as *Perez*, *Wirtz*, and *Wickard* were also "as applied" challenges, and were rejected by employing an analysis that focused on the class of activities and not the individual plaintiff's conduct.

Respondents attempt to limit *Wickard* to its specific facts. Br. 13-18. In every relevant respect, however, the cases cannot be distinguished. Like the wheat in *Wickard*, marijuana that is grown, distributed, and then possessed for personal "medical" consumption can also, at any step, be sold or distributed to others. Similarly, marijuana sought for "medical" consumption can be either bought or grown, and access to and prevailing conditions in the market will influence both consumption and the means of acquisition of the product. Given the fungibility of marijuana and similar products, Congress found that federal regulation of all marijuana, no matter what its asserted origin or destination, is necessary. 21 U.S.C. 801(5). As in *Wickard*, there is no basis for overriding that congressional determination. See 317 U.S. at 125 ("even if appellee's activity be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce"). Indeed, given Congress's goal of entirely eliminating the interstate market in Schedule I substances—as opposed to regulating a commodity's price, as in *Wickard*—the threat that unregulated local activity poses to a legitimate federal regulatory scheme is even greater here.

Respondents' efforts to distinguish *Wickard* are unavailing. Respondents assert (Br. 14-16) that the amount of wheat that Filburn produced for consumption on his farm was significant by comparison to the amount of marijuana cultivated in this case. That is no basis for distinguishing *Wickard*. This Court rejected Filburn's challenge even though it expressly assumed that Filburn's contribution to the demand for wheat "may be trivial by itself." 317 U.S. at 127. Moreover, for farmers covered by the Agricultural Adjustment Act (AAA), any production in excess of an allotment was regarded as "available for marketing" and subject to penalty. *Id.* at 119. And in light of Congress's goal of

eliminating interstate commerce in Schedule I substances, rather than merely regulating the prevailing price in that market, even relatively small amounts of "lawful" Schedule I substances could cripple the federal scheme, especially given the fungible nature of marijuana.

Respondents also urge (Br. 15) that "[s]imple arithmetic" confirms that most of Filburn's excess production was used to feed livestock on his farm rather than to bake bread for his family, and note that the farm itself was a commercial operation. This Court, however, decided the case on the premise that the "intended disposition of the crop here involved has not been expressly stated." 317 U.S. at 114. The intended disposition—feed versus bread—was not relevant to either this Court's holding or to the purpose of the AAA, which was designed to stabilize the price of wheat by regulating the amount available to be sold. Finally, respondents observe (Br. 14) that the quota system established by the AAA did not apply to farms on which the acreage planted to wheat did not exceed 15 acres. But that point was not discussed in the Court's Commerce Clause analysis and appears only in the Due Process ruling. See 317 U.S. at 130 & n.30.[2]

Respondents suggest in passing (Br. 13), supported by some of their amici (Institute for Justice Am. Br. 14-30; Alabama et al. Am. Br. 24-25), that *Wickard* and its progeny should be overruled. As this Court explained in *Lopez*,

[2] Contrary to respondents' suggestion (Br. 19), *Katzenbach* v. *McClung*, 379 U.S. 294 (1964), and *Heart of Atlanta* v. *United States*, 379 U.S. 241 (1964), do not support analyzing the effects on interstate commerce from respondents' activities as separate and apart from the overall scheme regulated under the CSA. Congress had determined that the provisions of Title II of the Civil Rights Act of 1964, 42 U.S.C. 2000a *et seq.*, would apply only to certain sub-categories of restaurants and motels, and the Court therefore considered the constitutionality of Title II as so drawn. *Heart of Atlanta*, 379 U.S. at 247-249; *McClung*, 379 U.S. at 298-299.

however, the "doctrinal change" ushered in by *Darby*, *Wickard* and similar decisions of that era reflected both "a recognition of the great changes that had occurred in the way business was carried on in this country," as well as "a view that earlier Commerce Clause cases artificially had constrained the authority of Congress to regulate interstate commerce." 514 U.S. at 556; *id.* at 568-574 (Kennedy, J., concurring). "[T]he Court as an institution and the legal system as a whole have an immense stake in the stability of [the Court's] Commerce Clause jurisprudence as it has evolved to this point." *Id.* at 574. Congress has relied on that jurisprudence in enacting laws such as the CSA, which has been in place for more than 30 years, and respondents identify no fundamental flaw in this Court's governing precedents.

3. Respondents' contention that their drug activities are beyond the reach of Congress's power under the Commerce and Necessary and Proper Clauses because they are "non-commercial" and separable from the overall commercial drug market would create a gaping hole in the CSA. It would render Congress impotent to apply the CSA to any "non-commercial" drug activity, including that undertaken for recreational purposes or to satisfy a drug dependence, regardless of whether the drug is a Schedule I substance such as marijuana, LSD, or heroin, or a Schedule II-V substance such as methamphetamine, morphine, or cocaine. The inherently economic nature of respondents' underlying conduct—drug manufacturing, distribution, and ensuing possession—does not depend on the type of drug involved, the ultimate purpose of the activity, or the overt furnishing of consideration. Such conduct is subject to regulation under the Commerce Clause because it substantially affects the interstate market for controlled substances.

That conclusion is amply supported by the congressional findings in the CSA. Congress found that local drug activity,

including manufacture, distribution, and possession, substantially affects interstate commerce because such activity swells market demand and supply, because controlled substances readily cross state lines in market transactions, and because illicit drugs cannot be differentiated with respect to their origin and intended destination. 21 U.S.C. 801(3)-(5). Respondents complain that those findings are not marijuana-specific. But those conclusions hold true regardless of the type of drugs involved or the use to which they are put. Moreover, Congress was specifically aware when it enacted the CSA that "[t]he extent to which marihuana should be controlled is a subject upon which opinions diverge widely," and that "[t]here are some who not only advocate its legalization but would encourage its use." H.R. Rep. No. 1444, 91st Cong., 2d Sess., Pt. 1, at 12 (1970). Congress nonetheless listed marijuana "under schedule I, as subject to the most stringent controls under the bill." *Id.* at 13. And Congress found that federal control over all intrastate drug activity for controlled substances, including marijuana, was "essential to the effective control" of interstate drug activity. 21 U.S.C. 801(6).

Respondents also fault Congress for not making particularized findings with respect to marijuana intended for purported medical use in accordance with state law. But Congress can hardly be faulted for failing to anticipate and address subsequently-enacted state laws passed in the face of (1) federal prohibitions against marijuana production, distribution, and possession and (2) the underlying congressional determination, still in effect, that there is no currently accepted medical use for marijuana in the United States. Such subsequently enacted state laws cannot give rise to new limits on federal authority. In any event, Congress was not silent in the face of state laws like California's. It responded with a statutory provision entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE,"

in which Congress "oppose[d] efforts to circumvent" the Food and Drug Administration (FDA) approval process "by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the [FDA]." Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761. Congress thus has specifically determined that the reasons for comprehensively regulating controlled substances under the CSA continue to apply with full force to marijuana intended for medical use, even when authorized by state law.

For these reasons, it is completely irrelevant that it is "uncontroverted" that respondents in this case are not engaged in commerce. Resp. Br. 38. Whatever the true nature of respondents' own activities, the difficulty of "controverting" claims that the drugs in any particular case were produced wholly intrastate, for non-monetary exchange, or for personal medical use, vividly illustrates why Congress enacted a comprehensive regulatory system for such drugs. See 21 U.S.C. 801(5). Moreover, the record affirmatively shows that respondents' home-grown drug activities cannot be divorced from the overall drug market regulated by Congress. Both respondents Raich and Monson were consumers of lawful drugs listed on Schedules II through V, before turning to marijuana, a Schedule I substance, U.S. Br. 27, and respondents' claims of medical necessity suggest that both would purchase marijuana illegally if necessary. See J.A. 59. Raich also admits to past marijuana purchases. U.S. Br. 27-38. Each of these facts confirms what Congress found: that activities such as respondents' displace market transactions and threaten to swell the illicit drug market.

4. Recognition of the validity of the CSA as applied to respondents' drug activities does not, as respondents contend, confer on Congress "a general police power" or permit Congress to regulate a "homeowner planting and tending roses in his or her backyard." Br. 20, 26; see Constitutional

Law Scholars Am. Br. 13-14, 21. Rather, respondents' activities comfortably fall within Congress's commerce power because the activities occur in or are closely related to the comprehensively regulated drug market.

Moreover, Congress rationally included such activities within the CSA's regulatory scheme in order to suppress supply and demand and, particularly with respect to Schedule I substances, to enforce the CSA's prohibition on interstate commerce in such substances by banning production, distribution, and possession by the ultimate user. U.S. Br. 22-32. Congress could, of course, subject other substances —even hallucinogenic roses—to similar restrictions to enforce a ban on interstate commerce in the commodity. Such bans are rare, however, presumably because the circumstances calling for them are rare and because such comprehensive bans are particularly susceptible to political checks. But in certain circumstances, where concerns about fungibility require a ban on production, distribution, and possession in order to effectuate a ban on interstate trafficking in contraband, Congress may judge such action necessary. Congress's judgment here was clearly rational. The CSA as a whole and as applied to respondents' activities is simply a "*general regulatory statute*" that "*bears a substantial relation to commerce*," and accordingly "the *de minimis* character of individual instances arising under that statute is of no consequence." *Lopez*, 514 U.S. at 558 (quoting *Wirtz*, 392 U.S. at 197 n.27); U.S. Br. 14-15.

Likewise, upholding the CSA as applied to respondents' activities does not undermine the Court's holdings in *Lopez* and *United States* v. *Morrison*, 529 U.S. 598 (2000). See Resp. Br. 19-23. In those cases, the Court was concerned about the attenuated relationship between the conduct at issue—possession of a gun near a school (*Lopez*) and violence against women (*Morrison*)—and interstate commerce. But there is nothing attenuated about the connection between a

ban on manufacturing, distribution, and possession of contraband and a ban on trafficking in that valuable commodity in commerce. Respondents' activities, like those in *Wickard*, "involve[] economic activity in a way that the possession of a gun in aschool zone does not." *Lopez*, 514 U.S. at 560. Accordingly, and unlike in *Lopez* and *Morrison*, federal regulation of those activities is an "essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Id.* at 561. For that precise reason, both of the lower courts, in striking the statutes at issue in *Lopez* and *Morrison*, explicitly distinguished those statutes from the CSA's prohibitions against home-grown production and local possession of marijuana. *Brzonkala* v. *Virginia Polytechnic Inst. & State Univ.*, 169 F.3d 820, 836 n.7 (4th Cir. 1999) (en banc), aff'd *sub nom. United States* v. *Morrison*, 529 U.S. 598 (2000); *United States* v. *Lopez*, 2 F.3d 1342, 1367 n.51 (5th Cir. 1993), aff'd 514 U.S. 549 (1995); U.S. Br. 21-22.

B. Congress May Constitutionally Regulate Respondents' Marijuana Activities Notwithstanding State Law

1. Relying on principles of federalism, respondents assert that the CSA should not be interpreted to prohibit conduct, such as respondents' drug activities, to the extent that it is authorized under State law. Br. 42-45. That argument, raised for the first time in respondents' brief on the merits, is baseless. Absent a "plain indication to the contrary," it is presumed that Congress "is not making the application of the federal act dependent on state law." *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989) (emphasis added); *Dickerson* v. *New Banner Inst., Inc.*, 460 U.S. 103, 119 (1983).

Nothing in the CSA overcomes that presumption. To the contrary, under the CSA, unlike in *Parker* v. *Brown*, 317

U.S. 341 (1943), and its progeny under the antitrust laws, on which respondents rely, Congress has subjected the private conduct at issue to a comprehensive regulatory regime administered by the Attorney General and imposed a closed system of distribution pursuant to federal law. That regime leaves no room for contrary state policies. See 21 U.S.C. 903 (preempting all state laws that pose a "positive conflict" with the CSA such that the state and federal law "cannot consistently stand together").

The CSA makes it a felony "to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance," "[e]xcept as authorized" by the CSA itself. 21 U.S.C. 841(a)(1). Respondents argue that the Doe respondents do not "distribute" marijuana but rather "dispense" it as authorized by California law. Br. 7 n.6. That distinction is irrelevant and mistaken. Both distribution and dispensation of marijuana are felonies unless the conduct complies with the CSA, 21 U.S.C. 841(a)(1), and the Doe respondents do not claim that they complied with the CSA. In any event, the CSA defines "dispense" as the delivery of any drug "pursuant to [a practitioner's] *lawful order*," 21 U.S.C. 802(10), and as this Court made clear in *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489-491 (2001), there is no such thing under the CSA as a lawful order for a person to receive a Schedule I substance outside the narrow confines of government authorized research. See 21 U.S.C. 823(f), 829, 841(a)(1).

Similarly, the simple possession of marijuana by all respondents is prohibited by the plain terms of 21 U.S.C. 844(a), which authorizes possession of a controlled substance only when it is obtained under a "valid" prescription order. The Act clearly refers to prescriptions and orders that are valid under the CSA. Such prescriptions can be issued only for drugs on Schedules II through V, 21 U.S.C. 829, and only in compliance with the specific requirements of the Act.

Moreover, nothing in California law purports to make the possession of marijuana lawful under federal law. Any such effort would be the plainest of Supremacy Clause violations, and there is no justification for giving state law such an effect under the guise of statutory interpretation. State law simply removes state criminal prohibitions against cultivation and possession of marijuana, and leaves federal law, and Congress's authority, untouched.

2. Respondents and their amici also contend that principles of federalism prevent Congress from invoking its Commerce Clause power to apply the CSA in a way that interferes with a State's exercise of its police power. Resp. Br. 39-42; Cal. Nurses Ass'n et al. Am. Br. 3-4, 17-18. That radical proposition, however, would invert the operation of the Supremacy Clause, significantly impair Congress's power under the Commerce Clause, and obstruct effectuation of the CSA whenever a State made a contrary policy choice about the extent to which a drug has medical utility or potential for abuse. Not surprisingly, it is well settled that the commerce power "can neither be enlarged nor diminished by the exercise or non-exercise of state power." *Darby*, 312 U.S. at 114; *Wirtz*, 392 U.S. at 196-197.

3. Respondents argue that penalties under California law for commercial or recreational activities involving marijuana would serve to mitigate the adverse consequences of holding that Congress may not apply the CSA to respondents' activities. Br. 21, 29-30 n.16, 34, 36-37; accord Reason Found. Am. Br. 5-23; Inst. for Justice Am. Br. 10; Alabama et al. Am. Br. 3-6, 25-30. But the fact that California imposes penalties on the sale of marijuana and its cultivation or possession for recreational purposes, see Cal. Health & Safety Code §§ 11357, 11358, 11360(a) (West 2004), does nothing to facilitate the effectiveness of the CSA's penalties for "simple possession," see 21 U.S.C. 844, in order to eradicate the market in illicit drugs. As our opening brief explained, those

federal penalties are crucial both in suppressing the demand for marijuana and other Schedule I drugs and in decreasing the supply of drugs that can be sold. U.S. Br. 24-26, 27-28. Such penalties also make enforcement of the ban on interstate commerce in such substances effective. If, as respondents urge, a possession or distribution charge could be defeated by an unrebutted claim that the marijuana was intended for personal "medical" use in compliance with state law, the government would have to rebut that claim in the context of a fungible commodity that, in light of its illicit nature, would not have any of the markings that lawful drugs are required to bear to indicate their proper manufacture, distribution, or dispensing (see 21 U.S.C. 352, 825).

Furthermore, while California law prohibits the sale of marijuana, it does not prohibit the purchase. See *People* v. *Peron*, 70 Cal. Rptr. 2d 20, 27 (Ct. App. 1998). As a result, a person who possesses marijuana for his own personal medical use would not be subject to prosecution even if he had purchased the marijuana from someone else. See, *e.g.*, *People* v. *Wright*, 18 Cal. Rptr. 3d 220, 222, 227 (Ct. App. 2004) (also recognizing defense to charge of unlawful transportation of marijuana). For the same reason, primary caregivers such as the Doe respondents presumably would not be subject to prosecution if they purchased marijuana to supply to someone else for personal medical use. And, significantly, a California Court of Appeal has held that caregivers may receive "bona fide reimbursement for their actual expense" in "cultivat[ing] or acquir[ing] the medicinal marijuana." *Peron*, 70 Cal. Rptr. 2d at 31. Thus, it is clear that there is a fundamental mismatch between what state law permits (which includes, for example, possession as a result of a commercial exchange) and conduct that respondents contend lies beyond the bounds of Congress's Commerce Clause authority.

The dramatic effects on marijuana commerce of exempting drug activity authorized by California law well illustrate how such a rule would significantly undermine the enforcement and effectiveness of the CSA. The California chapter of one of respondents' amici "estimates that there are now more than 100,000 legal Prop. 215 patients in California." *California Dispensaries Proliferate in California*, Cal. NORML Newsletter, Aug. 1, 2004 <http//www.canorml.org/news/dispensariesproliferate.html>. That is the number under a legal regime in which federal law criminalizes such activity.[3] Were this Court to affirm the decision below, there would be no criminal prohibition against the manufacture, distribution, or possession of marijuana by the 35 million residents of California as long as they have a "written or oral recommendation or approval" of a physician that "marijuana provides relief" for "any * * * illness." Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West 2004); *Wright*, 18 Cal. Rptr. 3d at 226 ("[T]he defendant need not prove he is seriously ill to invoke the [Compassionate Use Act]."); see U.S. Census Bureau, *California Quick Facts* (visited Nov. 16, 2004) <http//quickfacts.census.gov/qfd/states/06000.html>; see also *Measure 33 is Wrong Prescription on Marijuana*, Statesman Journal, Sept. 27, 2004, at 5C

[3] Respondents observe that the federal government rarely prosecutes individuals for simple possession of small amounts of marijuana. Br. 31-32. That fact, however, does not prove that such possession is not occurring as part of commercial transactions, that such possession does not have substantial effects on the marijuana market as a whole, or that the advent of legal (i.e., non-contraband) marijuana would not frustrate the prosecution of the manufacturing, distribution, and possession cases the federal government does bring. It simply shows that the government exercises prosecutorial discretion in seeking to impose criminal penalties (as opposed to the type of civil forfeiture that occurred here), and that the government relies on the existence of the criminal prohibitions in the CSA to serve as a strong deterrent to illegal activity.

("About 10,000 Oregonians now use marijuana with a doctor's prescription.").

Marijuana collectives pose even greater threats to the federal scheme. Marijuana "cultivation collectives or cooperatives" are currently proliferating in California under the apparent assumption that they are legal under state law as long as the marijuana is not sold outright. *California Dispensaries Proliferate in California, supra.* For example, in *County of Santa Cruz* v. *Ashcroft*, 314 F. Supp. 2d 1000, 1007 (N.D. Cal. 2004), appeal docketed, No. 04-16291 (9th Cir. June 25, 2004), a district court held that the Ninth Circuit's decision in the instant case barred enforcement of the CSA against a cooperative of 250 members who manufactured and distributed marijuana because the cooperative did not charge its members for the marijuana but simply collected voluntary contributions.

The government's enforcement efforts would also be significantly hampered by the fact that there are no production, quality, or dose standards that could be relied upon to demonstrate that an amount of marijuana exceeds quantities appropriate for asserted medical purposes. U.S. Br. 30-31. For instance, in *Wright*, 18 Cal. Rptr. 3d at 226, a state court overturned a conviction of a person who possessed in his vehicle over a pound of marijuana packaged in six bags along with a scale. The court reasoned that the jury was entitled to believe the defendant's claim that "he needs relatively large quantities of the drug because he prefers to eat, rather than smoke," marijuana to alleviate physical pain and emotional stress. *Ibid.* See also *United States* v. *Alden*, Nos. 02-10673 & 02-10674 (9th Cir. Mar. 30, 2004), slip op. 2 (ordering release of defendant appealing marijuana convictions arising out of his manufacture of more than 1500 marijuana plants because "it is asserted that the drug involved is marijuana, the use is for medicinal purposes, and the use is strictly local").

Moreover, whatever the outer bounds of lawful possession in the State, California law clearly authorizes patients and primary caregivers to possess in excess of eight ounces of dried marijuana per patient and six mature or 12 immature plants per patient as long as the quantity is permitted by the city or county or the quantity is "consistent with the patient's needs." Cal. Health & Safety Code § 11362.77(a), (b) and (c) (West 2004); cf. 86 Ops. Cal. Att'y Gen. 180 (2003) ("Proposition 215 was approved by the voters without specificity as to the strength, quality, or quantity of marijuana to be used for medical purposes.") (emphasis added). The relevant policy in the cities of Oakland and Santa Cruz and the counties of Sonoma and Tehama is to allow patients to possess up to three pounds of processed marijuana. *Proposition 215 Enforcement Guidelines* (visited Nov. 9, 2004) <http://www.canorml.org/prop/local215policies.html>. Those amounts are astonishingly large, as three pounds of marijuana yields approximately 2700 joints or cigarettes. DEA, U.S. Dep't of Justice, *DEA Agents Manual* App. E (2004). The regime contemplated by respondents therefore would render it exceedingly unlikely that the federal government would be able to enforce the CSA as to persons manufacturing, distributing, or possessing even large quantities of marijuana without firm proof of a commercial transaction or purpose, despite Congress's specific finding that controlled substances typically have or will enter the stream of commerce. 21 U.S.C. 801(3); U.S. Br. 31-32.

It thus is highly implausible that existing state-law prohibitions against commercial or recreational marijuana activities would protect the regulatory scheme as envisioned by Congress. California law rests on fundamentally different assumptions about the risks and benefits of marijuana. Moreover, California law imposes none of the stringent production, order form, prescription, record-keeping, labeling, packaging, and diversion controls that the CSA places on

controlled substances that (unlike marijuana) Congress has deemed to have an accepted and legitimate medical use. 21 U.S.C. 821-829. The regime urged by respondents and embraced by the Ninth Circuit's decision would therefore completely undermine the CSA's comprehensive, uniform, and closed system of regulation that is intended to protect both interstate commerce and the public health and safety, and would have a staggering effect on the interstate marijuana market and congressional control over that market.

C. The Preliminary Injunction Cannot Be Affirmed on Alternative Grounds.

Respondents assert that the decision below may be affirmed on the alternative basis of a supposed "non-constitutional doctrine of medical necessity," Br. 46, as well as on Fifth Amendment grounds, Br. 48-50. The district court rejected those contentions, Pet. App. 58a-65a, but the court of appeals did not address them, *id.* at 9a. This Court, therefore, should not reach them either. See, *e.g.*, *Oakland Cannabis*, 532 U.S. at 494.

Respondents' arguments are, in any event, without merit. This Court in Oakland Cannabis specifically rejected not only a medical necessity defense but also any distinction between a claimed medical necessity to manufacture and distribute marijuana and a claimed medical necessity to possess it. 532 U.S. at 494 n.7. Moreover, this case involves the manufacture and distribution of marijuana, as well as its possession.

Respondents' Fifth Amendment argument fares no better. There is no fundamental right to use marijuana for medicinal purposes in the face of Congress's placement of marijuana in Schedule I based on a determination that marijuana has "no currently accepted medical use for treatment in the United States" and has a high potential for abuse. 21 U.S.C. 812(b)(1)(A)-(C); cf. *United States* v. *Rutherford*, 442

U.S. 544 (1979). Congress has established procedures to remove drugs from Schedule I if they no longer satisfy the criteria for that schedule (21 U.S.C. 811), and has provided the FDA with authority to approve a drug product containing marijuana should it be shown to be safe and effective for any medical use (21 U.S.C. 355). Congress also permits individuals to participate in research projects that have been registered with the DEA and approved by the FDA. 21 U.S.C. 355(i), 823(f). Respondents do not assert that they have invoked any of those statutory mechanisms.[4]

* * * * *

For the foregoing reasons and those stated in the opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

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NOVEMBER 2004

[4] In disagreeing with Congress's judgement that marijuana has no medical utility, respondents and their amici principally rely on the report of the Institute of Medicine (IOM) that reviewed the existing scientific evidence concerning possible medical uses of marijuana and recommended that further research be devoted, not to developing marijuana as a licensed drug, but to developing a method of delivering cannabinoids without the serious adverse health consequences associated with smoking marijuana. IOM, *Marijuana and Medicine: Assessing the Science Base* 10-11 (Janet E. Joy et al. eds. 1999) ("Because marijuana is a crude THC delivery system that also delivers harmful substances, smoked marijuana should generally not be recommended for medical use."). Similarly, although respondents point out that Marinol is a lawful drug that contains *THC* (Br. 4 n.4), respondents do not (and could not) dispute that *marijuana* is a Schedule I controlled drug that has never been approved for any medical use by the FDA. See U.S. Pet. 17 n.4; U.S. Br. 41-42 n.5.

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Supreme Court of the United States

JOHN D. ASHCROFT, ATTORNEY GENERAL, *et al.*,
Petitioners,

v.

ANGEL MCCLARY RAICH, *et al.*,
Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Ninth Circuit

BRIEF OF THE STATES OF ALABAMA, LOUISIANA, AND MISSISSIPPI AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. §801 *et seq.*, exceeds Congress' power under the Commerce Clause as applied to the intrastate possession and manufacture of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use. *See* Pet. at i.

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Ala. Code §20-2-22 4

Ala. Code §20-2-23 4

Controlled Substances Therapeutic Research Act, Acts 1979, No. 79-472 (codified at Ala. Code §20-2-110 *et seq.*) 5

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INTEREST OF AMICI

The Court should make no mistake: The States of Alabama, Louisiana, and Mississippi do *not* appear here to champion (or even to defend) the public policies underlying California's so-called "compassionate use" law. As a matter of drug-control policy, the amici States are basically with the Federal Government on this one. We agree wholeheartedly that drug abuse is one of the Nation's "most important public health problem[s]"[1] and is "undercutting traditional values and threatening the very existence of stable families, communities, and government institutions,"[2] and we are fully committed to partnering with the Federal Government in a vigorous prosecution of the war on drugs.

This, accordingly, is not a brief of "[d]rug legalization advocates"[3] or "pro-marijuana activists."[4] Far from it. With respect to the issue at hand, the amici States' Legislatures have enacted, their Attorneys General have enforced, and their courts have routinely sustained statutes broadly criminalizing marijuana possession and, depending on the circumstances, punishing violators with up to 10 years in prison for a first offense. *See, e.g.*, Ala. Code §§13A-5-6, 13A-5-7, 13A-12-213, 13A-12-214. Indeed, the lead amicus here, Alabama, has apparently earned something of a reputation for its zeal in prosecuting and punishing drug crimes. *See* E. Nadelmann, *An End to Marijuana Prohibition*, National Review, p.28 (July 12, 2004) ("Alabama currently locks up people convicted three times of marijuana possession for 15 years to life."). It is not a reputation of which Alabama is embarrassed or ashamed. On the contrary, Alabama's Attorney General has every intention of continuing to prosecute drug crimes to the fullest extent of the law.

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[1] Br. of U.S. Representatives as Amici Curiae at 3 ("Reps' Br.").
[2] Br. of the Drug Free America Found., *et al.*, as Amici Curiae at 1 ("Drug Free Br.").
[3] Drug Free Br. 9.
[4] Reps' Br. 15.

Drug-control policy aside, the amici States also disagree with respondents' contention that there is embedded in the Constitution (whether in the Due Process Clause, the Ninth Amendment, or elsewhere) a "fundamental right" – however defined – to smoke or otherwise ingest marijuana. Alabama, for instance, has consistently urged this Court not to divine new, unenumerated rights from the Constitution's open-textured provisions and, instead, to leave difficult social policy choices to elected state legislatures. *See, e.g.*, Br. of the States of Alabama, *et al.*, *Roper v. Simmons*, No. 03-633; Br. for the States of Alabama, *et al.*, as Amici Curiae, *Lawrence v. Texas*, 539 U.S. 558 (2003) (No. 02-102); Br. for Amici Curiae States of California, Alabama, *et al.*, *Washington v. Glucksburg*, 521 U.S. 702 (1997) (No. 96-110). The amici States' position here is no different.

From the amici States' perspective, however, this is not a case about drug-control policy or fundamental rights. This is a case about "our federalism," which "requires that Congress treat the States in a manner consistent with their status as residuary sovereigns and joint participants in the governance of the Nation." *Alden v. Maine*, 527 U.S. 706, 748 (1999). The Government apparently does not view the federalism issue in this case as a serious one. *See* U.S. Br. 13 ("*It is clear* that Congress has the authority ...." (emphasis added)). We respectfully disagree. And, just as individual States have intervened to challenge laudatory (and popular) congressional statutes on federalism grounds before, *see, e.g.*, Br. for the State of Alabama as Amicus Curiae, *United States v. Morrison*, 529 U.S. 598 (2000) (Nos. 99-5, 99-29), the amici States perceive a need to do so here.

While the amici States may not see eye to eye with some of their neighbors concerning the wisdom of decriminalizing marijuana possession and use in certain instances,[5] they support their neighbors' prerogative in

[5] The State of Louisiana, which has enacted a statute permitting the medicinal use of marijuana in very limited circumstances, joins in the Argument section of this brief.

our federalist system to serve as "laboratories for experimentation." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring). As Justice Brandeis famously remarked, "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). Whether California and the other compassionate-use States are "courageous" – or instead profoundly misguided – is not the point. The point is that, as a sovereign member of the federal union, California is entitled to make for itself the tough policy choices that affect its citizens. By stepping in here, under the guise of regulating interstate commerce, to stymie California's "experiment[]," Congress crossed the constitutional line.

ALABAMA'S DRUG-CONTROL REGIME

All of the amici States have adopted – and vigorously enforce – broad prohibitions on marijuana possession and use. *See generally* Appendix, *infra*. The States' precise prohibitions and enforcement strategies, of course, are not identical in every jot and tittle. The following description of Alabama's drug-control regime, however, is illustrative of the way in which the amici States have tackled the marijuana-possession problem.

A. Alabama's Criminal Statutes

In a portion of the criminal code devoted to "Offenses Against Public Health and Morals," Alabama law comprehensively prohibits the cultivation, possession, sale, distribution, and trafficking of marijuana. *See* Ala. Code §13A-12-210 *et seq*. Under Alabama law, as under the U.S. Code, marijuana is a "Schedule I" drug, meaning it has a "high potential for abuse" and has "no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical

supervision," *id.* §§20-2-22, 20-2-23 (referenced in *id.* §13A-12-216).

As relevant here, a person is guilty under Alabama law of "Unlawful possession of marihuana in the second degree," a Class A misdemeanor punishable by up to a year in prison, if he possesses marijuana for personal use. *Id.* §§13A-12-214, 13A-5-7. A person commits the crime of "Unlawful possession of marihuana in the first degree," a Class C felony punishable by up to 10 years in prison, if he (i) possesses marijuana for other than personal use or (ii) possesses marijuana for personal use after having been previously convicted of personal-use possession. *Id.* §§13A-12-213, 13A-5-6. Additionally, a person is guilty of the "Unlawful distribution of controlled substances," a Class B felony punishable by up to 20 years in prison, if he "sells, furnishes, gives away, manufactures, delivers, or distributes [any] controlled substance," including marijuana. *Id.* §§13A-12-211, 13A-5-6. At the Attorney General's urging, Alabama courts have broadly construed these statutes – for instance, to allow for conviction on a theory of "constructive possession." *See, e.g., Gray v. State*, 600 So. 2d 1076, 1078 (Ala. Crim. App. 1992).

Respondents' conduct – cultivating and possessing marijuana for personal consumption – would thus plainly be criminal in the State of Alabama. Notably for present purposes, Alabama courts have – again, at the Attorney General's urging – expressly refused to recognize "'medical necessity' as a valid defense in a prosecution for the unlawful possession of marijuana." *Kauffman v. State*, 620 So. 2d 90, 93 (Ala. Crim. App. 1992). The defendant in *Kauffman* alleged that he suffered from "uncontrollable muscle spasms and associated crippling symptoms of an affliction that [was] progressing from paraplegia to quadriplegia" and that "marijuana [was] the only medication that w[ould] relieve his pain and suffering." *Id.* at 91. Despite the sympathy that the defendant's condition unquestionably engendered, the court, after canvassing the relevant statutes and common-law precedents, held that "the Alabama Legislature ha[d]

precluded the appellant's use of the defense of medical necessity ...." *Id.* at 92.[6]

B. Alabama's Law-Enforcement Efforts

In the war on drugs, Alabama is not standing pat. To the contrary, both state and local law-enforcement agencies in Alabama have devoted substantial resources to the investigation and prosecution of narcotics offenses. At the state level, Alabama's Department of Public Safety includes two units – the Alabama Bureau of Investigation and the Highway Patrol Division – that target drug crime. *See* Alabama Department of Public Safety, www.dps.state.al.us. At the local level, many police and sheriffs' departments in Alabama operate dedicated narcotics units. *See, e.g.*, City of Birmingham – Police Department, Vice and Narcotics Unit, www.information.birmingham.com/police/vicenar.htm ("Birmingham PD Report"); Huntsville Police Department – Priorities in Focus: Drugs, www.ci.huntsville.al.us/police/drugs.htm; Baldwin County Sheriff's Department, Narcotics Division, www.sheriff.co.baldwin.al.us. Other local jurisdictions have banded together to form joint task forces to combat drug crime more efficiently. *See, e.g.*, Madison-Morgan County Strategic Counterdrug Team, www.drugteam.net; Barbour/Bullock County Drug Task Force, www.bcdtf.com; West Alabama Narcotics Task Force, www.ci.tuscaloosa.al.us/pdinfo.htm.

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[6] Interestingly enough, Alabama has dealt with the issue of medical marijuana before. In 1979, the Alabama Legislature enacted the Controlled Substances Therapeutic Research Act. *See* Acts 1979, No. 79-472, p.870 (codified at Ala. Code §20-2-110 *et seq.*). That Act established within the state Board of Medical Examiners a research program, pursuant to which an "authorized practitioner" could "certif[y]" a chemotherapy or glaucoma patient for strictly supervised cannabis-based treatment. Ala. Code §20-2-114. The research program, however, never really got off the ground and, although it technically remains on the books, is by all accounts defunct today. We are informed by the Board of Medical Examiners that there are no patients presently participating in the program and, indeed, that the program's cannabis-prescription apparatus is non-existent and that no practitioner is currently certified by the Board to dispense cannabis.

Not surprisingly, these vigorous enforcement efforts have paid dividends – particularly (as relevant here) on the marijuana-possession front. During 2003 alone, state and local law-enforcement officers arrested 16,524 persons for drug-related offenses. That is more than the number of persons arrested for DUI (14,173) and larceny (15,935) – and, indeed, is more than the number of persons arrested for homicide, rape, assault, burglary, robbery, arson, and car theft *combined*. Notably for present purposes, "marijuana possession resulted in the greatest number of arrests for drug violations"; there were 9469 marijuana-possession arrests in 2003, a figure that represents 57% of all drug-related arrests. *See* 2003 Crime in Alabama, Alabama Criminal Justice Information Center, www.acjic.state.al.us/sac.[7] Statistics for each of the previous eight years are to the same effect:

Year	Drug Arrests	Marijuana. Poss. Arrests
2002	15,493	9105 (59%)
2001	14,295	8953 (63%)
2000	14,890	9658 (65%)
1999	16,492	10,566 (64%)
1998	17,516	10,573 (60%)
1997	16.345	10,008 (61%)
1996	15,580	8981 (58%)
1995	13,201	7723 (59%)

See Statistical Analysis Center, Alabama Criminal Justice Information Center, www.acjic.state.al.us/sac.

What these data show is that Alabama's focus on drug crime generally, and on marijuana possession specifically, is no passing fancy. To the contrary, Alabama's campaign has been, and will continue to be, sustained and vigilant.

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[7] In addition, between July 2003 and July 2004, Alabama Highway Patrol officers made 482 marijuana-possession arrests. *See* Alabama Department of Public Safety, AST Violation Tally Ticket Summary.

SUMMARY OF ARGUMENT

The question presented here is not whether vigorous enforcement of the Nation's drug laws is good criminal policy. It most assuredly is. The question, rather, is whether the Constitution permits the Federal Government, under the guise of regulating interstate commerce, to criminalize the purely local possession of marijuana for personal medicinal use. It does not.

1. A straightforward application of the principles outlined in *Lopez* and *Morrison* shows that Congress crossed the constitutional line when it criminalized the purely local possession of marijuana for personal use. First, like gun possession, marijuana possession is not inherently an "economic activity." Second, the Controlled Substances Act provision at issue lacks a jurisdictional hook; it purports to regulate local possession per se, without respect to any connection to interstate commerce. Third, although Congress made several generic findings in the text of the CSA concerning the interstate effects of local drug activity (*e.g.*, that drugs possessed locally "commonly flow through interstate commerce"), those findings are not entitled to deference here both (i) because they are unsupported by any hard data in the legislative record and (ii) because they do not address marijuana that, like respondents', is produced intrastate, possessed intrastate, and consumed intrastate.

2. *Wickard v. Filburn* is not the panacea the Government thinks, for three reasons. First, *Lopez* and *Morrison* make clear that *Wickard*'s aggregation principle does not apply where, as here, the activity subject to federal regulation is not "economic." Second, and in any event, it is just not true that *Wickard* is on all fours here. Contrary to popular misconception, *Wickard* was not about a farmer growing wheat in his back yard to bake a few loaves of bread. Farmer Filburn owned a large and multifaceted farming operation; during the year in question, he harvested nearly 28,000 pounds of wheat. Moreover, careful attention to the economic and agricultural facts underlying *Wickard* shows that the

"home consumption" to which the Court in that case referred was, at least principally, Filburn's use of large quantities of wheat to feed livestock and poultry, which he then sold on the open market. Had *Wickard* really been just about Filburn's bread-baking, it is inconceivable to us that it would have come out the same way. Because the Government here seeks to apply the CSA's criminal prohibitions to respondents' simple possession of a few marijuana plants, its theory would carry the Court well beyond *Wickard* and into uncharted Commerce-Clause waters. Finally, to the extent that *Wickard* can be read to justify direct federal regulation of respondents' purely local possession, it should be overruled.

3. The Government's "frustration of purpose" argument – that without authority over local activity Congress cannot efficiently regulate interstate drug trafficking – likewise fails for several reasons. First, it is not (and does not purport to be) a *constitutional* argument; the fact that direct control over local activity may facilitate congressional objectives has little, if anything, to do with the anterior question whether Congress has constitutional authority to exert direct control. Second, the Government has offered no evidence – statistical, anecdotal, or otherwise – to support its assertion that direct control over local activity is "essential" to federal drug policy. Finally – and most importantly from the States' perspective – the Government's various arguments about the imperative of effective drug-control policy *completely ignore the ongoing efforts of state and local law enforcement.* The Government's assertion of federal power here seems rather plainly to rest on the assumption that absent federal control, anarchy would reign at the local level. That assumption is (to say the least) unwarranted.

ARGUMENT

This case presents the question the Court reserved in *United States v. Oakland Cannabis Buyers' Cooperative* – namely, whether, as applied to what all here agree is the purely local cultivation and possession of marijuana for personal, noncommercial use, the Controlled Substances Act ("CSA") "exceeds Congress' power under the Commerce Clause." 532 U.S. 483, 495 n.7 (2001). The question is a narrow one: whatever the outcome here, the amici States agree that Congress enjoys wide latitude in regulating the "quintessentially commercial" aspects of the drug trade (*e.g.*, manufacture and distribution for consideration). U.S. Br. 18. The issue here is simply whether Congress' effort to extend its power under the "interstate" Commerce Clause to conduct that is *neither* interstate *nor* commerce is a bridge too far. *Cf. National Ass'n of Home Builders v. Babbitt*, 130 F.3d 1041, 1061 (D.C. Cir. 1997) (Sentelle, J., dissenting) (comparing extension of interstate-commerce power to conduct that is neither interstate nor commerce to "the old chestnut: If we had some ham, we could fix some ham and eggs, if we had some eggs").

The resolution of the question presented turns on the "first principles" of our federal system. *United States v. Lopez*, 514 U.S. 549, 552 (1995). First, whereas the powers that are reserved to the States under the Constitution are "numerous and indefinite," those delegated to the Federal Government are "few and defined." *The Federalist* No. 45, at 292-93 (C. Rossiter ed., 1961). Second, it is so that the limitations on federal power "may not be mistaken or forgotten [that] the constitution is written." *Marbury v. Madison*, 5 U.S. (1 Cranch.) 137, 176 (1803). And third, "courts of justice" must be "bulwarks of a limited Constitution against legislative encroachments" and invalidate enactments that go too far. *The Federalist* No. 78, at 469. However sound as a matter of policy, the laws at issue – which, among other things, make "simple drug possession" (U.S. Br. 11) a federal criminal offense – go too far.

This case arises against the backdrop of the States' unquestioned "police power" to make and enforce laws protecting the health, safety, welfare, and morals of their citizens. Indeed, of the "numerous" powers reserved to the States under the Constitution, one of the most fundamental is the power to define and punish criminal conduct. This Court has recently reiterated that "[u]nder our federal system, the '"States possess primary authority for defining and enforcing the criminal law,"'" *Lopez*, 514 U.S. at 561 n.3 (quoting *Brecht v. Abrahamson*, 507 U.S. 619, 635 (1993) (quoting *Engle v. Isaac*, 456 U.S. 107, 128 (1982))), and, further, that "criminal law enforcement" is an area "where States historically have been sovereign," *id.* at 564; *see also id.* at 580 (Kennedy, J., concurring) (criminal law an "area of traditional state concern"). It has long been recognized, by contrast, that Congress has no power to "punish felonies generally," *Cohens v. Virginia*, 19 U.S. (6 Wheat.) 264, 428 (1821), and does not enjoy anything approaching a general police power over citizens' health and safety, *see United States v. Morrison*, 529 U.S. 598, 618-19 & n.8 (2000).

This case illustrates precisely how an overreaching federal criminal statute – again, however well-intentioned – can undermine state prerogatives. Many States, the amici States among them, already outlaw marijuana possession in essentially all circumstances. *See supra* at 3-5 (Alabama); *see also* La. Rev. Stat. Ann. 40:966(C); Miss. Code Ann. §41-29-139(c). This Court has recognized that where, as here, Congress "criminalizes conduct already denounced as criminal by the States, it effects a '"change in the sensitive relation between federal and state criminal jurisdiction."'" *Lopez*, 514 U.S. at 561 n.3 (quoting *United States v. Enmons*, 410 U.S. 396, 411-12 (1973) (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971))); *see also Jones v. United States*, 529 U.S. 848, 859-60 (2000) (Stevens, J., concurring) (noting federal arson statute's "overlap with state authority"). Following Justice Kennedy's logic in *Lopez*, where "over 40 States already ha[d] criminal laws outlawing the possession of

firearms on or near school grounds," if a State determines (as many have) "that harsh criminal sanctions are necessary and wise to deter" marijuana possession, "the reserved powers of the States are sufficient to enact those measures." 514 U.S. at 581 (Kennedy, J., concurring).

Just as the CSA unnecessarily duplicates the criminal regimes of many States, it "effectively displaces" the "policy choice[s]" made by others. *Jones*, 529 U.S. at 859 (Stevens, J., concurring). In striking down the Gun Free School Zones Act in *Lopez*, this Court emphasized the Government's concession that the Act "'displace[d] state policy choices in ... that its prohibitions appl[ied] even in States that ha[d] chosen not to outlaw the conduct in question.'" 514 U.S. at 561 n.3 (quoting Br. for United States 29 n.18). So, too, the CSA countermands state policy choices and substitutes a uniform federal rule. Several States – California among them – have chosen to enact medical-use exceptions to their general marijuana-possession prohibitions. Again, the point is not whether a medical-use exception is sound criminal policy (the amici States are convinced it is not). Rather, the point is that, in our federalist system, a State has the right to set its own criminal policy free of congressional interference.

I. A Straightforward Application Of *Lopez* And *Morrison* Demonstrates That The CSA May Not Be Applied To Purely Local Activity.

In its recent Commerce-Clause decisions, this Court has enumerated guideposts for determining whether an activity sufficiently "substantially affects" interstate commerce to permit congressional regulation. *See Morrison*, 529 U.S. at 610-13. Those guideposts – which, notably, the Government's brief does not analyze in any systematic way – point decisively toward a finding of unconstitutionality here.

1. *Economic Activity.* This Court has emphasized that in every instance in which it has permitted federal regulation of local activity on the ground that it substantially affects interstate commerce, "the activity in

question has been some sort of economic endeavor." *Id.* at 611. As examples, the Court in *Lopez* pointed to decisions allowing federal regulation of, for instance, coal mining, credit transactions, restaurants, and hotels. 514 U.S. at 560. By contrast, the statute the Court faced in *Lopez*, which criminalized the possession of guns in school zones, "ha[d] nothing to do with 'commerce' or any sort of economic enterprise, however broadly one might define those terms." *Id.* at 561. "The possession of a gun in a local school zone," the Court emphasized, "is in no sense an economic activity" that might affect interstate commerce. *Id.* at 567. Even *Wickard v. Filburn*, 317 U.S. 111 (1942) – of which more later – "involved economic activity in a way that the possession of a gun in a school zone does not." 514 U.S. at 560. *Morrison* is to the same effect. In striking down a portion of the Violence Against Women Act, this Court there emphasized that "[g]ender-motivated crimes of violence are not, in any sense of the phrase, economic activity." 529 U.S. at 613.

What was true in *Lopez* and *Morrison* is equally true here. The activity that Congress seeks to regulate – the purely local cultivation, possession, and personal use of marijuana – is "beyond the realm of commerce in the ordinary and usual sense of that term." *Lopez*, 514 U.S. at 583 (Kennedy, J., concurring); *see also id.* at 599 (Thomas, J., concurring) ("wholly separated from business"). To be sure, there is a vibrant interstate market in illegal drugs; it would be naïve to pretend otherwise. *See, e.g.*, U.S. Br. 19 ("The interstate market for marijuana that Congress regulates under the CSA is well-established and substantial."). But that was the case in *Lopez*, as well; surely the interstate gun market is no less robust than the interstate drug market. And just as the firearms statute at issue in *Lopez* was aimed not at the commercial aspect of the gun "market," but instead at protecting the welfare of schoolchildren, the CSA is not intended (at least primarily) to strike at the commercial aspect of the drug trade, but instead to minimize the harmful effects that accompany drug use. *Cf. United*

States v. Stewart, 348 F.3d 1132, 1137 (9th Cir. 2003) (Kozinski, J.) (federal machine-gun ban intended to keep guns out of the hands of criminals, not to regulate the economics of the "machinegun business").

The Government contends that respondents' conduct here is "economic activity that is subject to congressional control because it occurs in, and substantially affects, the marijuana market generally." U.S. Br. 12. But that argument blurs together two distinct requirements of valid Commerce-Clause legislation. To be the proper subject of federal regulation, a local activity must both (i) be "economic" in its own right and (ii) "substantially affect[]" interstate commerce. *See Lopez*, 514 U.S. at 560 ("Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained."). By arguing that respondents' conduct is economic *because* it affects interstate commerce, the Government elides the economic-activity limitation that this Court's cases plainly establish.

The Government's argument, in any event, cannot overcome the basic point here that, as in both *Lopez* and *Morrison*, "[n]either the actors nor their conduct" – nor, for that matter, the purpose underlying the challenged statute – "has a commercial character ...." *Lopez*, 514 U.S. at 581. Respondents here are not trafficking in marijuana; nor do they pay for the marijuana they use. Rather, respondents cultivate and possess small amounts – infinitesimal, in the grand scheme – of marijuana purely for personal use. *See* Pet. App. 6a (six cannabis plants). Respondents' "simple drug possession" (U.S. Br. 11) may well be condemnable; what it is *not* is economic or commercial in any meaningful sense. *See Lopez*, 514 U.S. at 580 (Kennedy, J., concurring) ("simple possession of a gun"); *id.* at 585 (Thomas, J., concurring) ("mere gun possession").

Under this Court's precedent, the fact that Congress here has purported to regulate "noneconomic, criminal" conduct is a "central," if not altogether sufficient, reason

for invalidating the CSA's application to respondents' purely local activities. *Morrison*, 529 U.S. at 610.

2. *Jurisdictional Element.* A second guidepost is easily discerned, and likewise points toward invalidity. The CSA makes it a federal crime "to manufacture, distribute, [or] dispense," or even "to possess," a controlled substance except as expressly authorized by the CSA itself. 21 U.S.C. §841(a), 844(a). Like the statutes struck down in *Lopez* and *Morrison* – and unlike the statute upheld in *United States v. Bass*, 404 U.S. 336 (1971) – the CSA contains "no express jurisdictional element which might limit its reach to a discrete set" of offenses "that additionally have an explicit connection to or effect on interstate commerce." *Lopez*, 514 U.S. at 562. Rather, it regulates, for instance, local cultivation and possession per se, without respect to any connection to commerce. *Cf. Bass*, 404 U.S. at 339 n.4 (recognizing constitutional question whether Congress may criminalize "mere possession"); *United States v. Five Gambling Devices*, 346 U.S. 441, 448 (1953) (plurality opinion) (same).

3. *Congressional Findings.* There is no disputing that Congress made certain findings in the body of the CSA concerning the interstate effects of intrastate drug activity. *See* U.S. Br. 4-5 (quoting 21 U.S.C. §801). For three reasons, however, Congress' findings provide an insufficient basis to sustain the CSA's application here. First, as the State of Alabama urged and as this Court held in *Morrison*, "the existence of congressional findings is not sufficient, by itself, to sustain the constitutionality of Commerce Clause legislation." 529 U.S. at 614. "'"Simply because Congress may conclude that a particular activity substantially affects interstate commerce does not necessarily make it so."'" *Id.* (quoting *Lopez*, 514 U.S. at 557 n.2 (quoting *Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc.*, 452 U.S. 264, 311 (1981) (Rehnquist, J., concurring in judgment))). In our system of checks and balances, Congress is not "the constitutional judge[] of [its] own powers" and cannot render constructions of laws "conclusive upon the other

departments." *The Federalist* No. 78, at 467. It remains this Court's responsibility "to say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

Second, the Court should be, if anything, more reluctant here than in *Morrison* to defer to congressional findings. In that case, Congress' findings concerning the interstate effects of gender-based violence were by Alabama's own admission "extensive"[8]; by the Court's estimation "numerous," 529 U.S. at 614; and in Justice Souter's view supported by a "mountain of data," *id.* at 628 (Souter, J., dissenting). Specifically, as Justice Souter emphasized –

- passage of the Violence Against Women Act "was preceded by four years of hearings, which included testimony from physicians and law professors; from survivors of rape and domestic violence; and from representatives of state law enforcement and private business";
- the record there "include[d] reports on gender bias from task forces in 21 States"; and
- the Court there had "the benefit of specific factual findings in the eight separate Reports issued by Congress and its committees over the long course leading to enactment."

Id. at 628-31. Even so – and in our view rightly so – the Court in *Morrison* refused to defer to Congress' findings. The same reluctance should follow *a fortiori* here, where there seems to be nothing approaching a "mountain of data" justifying direct federal control of local activity. While there is apparently an extensive legislative record on the scope of the drug problem generally (U.S. Br. 18-20), that is not the issue here. The Government has pointed to nothing in the legislative history of the CSA that goes beyond rote recitation of the findings contained in §801 to provide a reasoned evidentiary basis for direct

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[8] *See* Br. for the State of Alabama at 15.

federal control of local conduct. *See, e.g.*, U.S. Br. 2, 3, 17, 18, 19, 23, 29, 34, 39-40.

Finally, and in any event, the findings on which the Government relies are insufficient to justify application of the CSA in this case. Some simply do not apply at all. For instance, while it may be true that "after manufacture, *many* controlled substances are transported in interstate commerce," that "controlled substances distributed locally *usually* have been transported in interstate commerce immediately before their distribution," and that "controlled substances possessed *commonly* flow through interstate commerce immediately prior to such possession," 21 U.S.C. §801(3)(A)-(C) (emphasis added), none of those things, apparently, is true of the marijuana at issue here. By contrast, the record in this case shows that respondents' marijuana is produced intrastate, possessed intrastate, and consumed intrastate. *See* Br. in Opp. 6-7 ("Angel Raich's cannabis is grown using only soil, water, nutrients, growing equipment, supplies, and lumber originating from or manufactured within California. ... Diane Monson's 'cultivation of marijuana is similarly local in nature.'" (quoting Pet. App. 47a)).

Other findings seem rather plainly at odds with the core theory of the Government's case. For instance, Congress found that local possession of controlled substances would have a tendency to "swell[] the interstate traffic" in those substances. 21 U.S.C. §801(4). And, in fairness, at times the Government contends that local use and possession will "increase[] demand" for marijuana. U.S. Br. 24. But fundamentally, it seems, the Government relies on *Wickard v. Filburn*, 317 U.S. at 127, for the proposition that by cultivating and consuming one's own product (wheat there, marijuana here) an individual "forestall[s] resort to" – and thus *reduces* demand in – the interstate market. *See* U.S. Br. 38-39.

In sum, the *Lopez* and *Morrison* factors counsel strongly against the Government's position here.

II. *Wickard v. Filburn* Does Not Justify The CSA's Application To Purely Local Activity.

Rather than seeking to defend the application of the CSA under the factors enunciated in *Lopez* and *Morrison*, the Government pins its hopes principally on *Wickard v. Filburn*, 317 U.S. 111, which this Court has called "perhaps the most far reaching example of Commerce Clause authority over intrastate activity." *Lopez*, 514 U.S. at 560. The Government leads off its argument with a citation to *Wickard* (U.S. Br. 10); describes *Wickard* as a case about the production of wheat "for personal use" (U.S. Br. 16); and, accordingly, contends that the constitutionality of the CSA's application to purely personal possession and use "follows from" *Wickard* (U.S. Br. 21).

Specifically, the Government seeks the benefit of *Wickard*'s "aggregation" principle. In *Wickard*, this Court sustained federal legislation regulating wheat, including wheat "consumed on the farm," on the ground that by "meet[ing] his own needs" a wheat farmer could "forestall resort to" – and thus reduce demand in – the interstate wheat market. 317 U.S. at 127. In so doing, the Court noted that the fact that a single farmer's "own contribution to the demand for wheat may be trivial by itself is not enough to remove him from the scope of federal regulation where, as here, his contribution, *taken together with that of many others similarly situated*, is far from trivial." *Id.* at 127-28 (emphasis added).

The Government's reliance on *Wickard* is misplaced for three reasons.

A. *Wickard*'s Aggregation Principle Does Not Apply Where, As Here, The Activity Subject To Federal Regulation Is Not "Economic."

In both *Lopez* and *Morrison*, this Court expressly refused to employ *Wickard*'s aggregation principle to validate congressional efforts to regulate intrastate, noneconomic activity. *See Morrison*, 529 U.S. at 611, 613;

Lopez, 514 U.S. at 560-61. And indeed, the Court in *Morrison* emphasized that "in every case where we have sustained federal regulation under the aggregation principle of *Wickard*" – including, by definition, *Wickard* itself – "the regulated activity was of an apparent commercial character." 529 U.S. at 611 n.4. Accordingly, in concluding its Commerce-Clause analysis in *Morrison*, this Court expressly "reject[ed] the argument that Congress may regulate noneconomic, violent criminal conduct based on that conduct's aggregate effect on interstate commerce." *Id.* at 617.

That statement controls this case, and precludes the Government's reliance on *Wickard*'s rule of aggregation. (There is certainly no principled reason why the rule allowing aggregation should be any more available with respect to noneconomic, nonviolent crime than with respect to noneconomic, violent crime. It was not the *violent* nature, but rather the *noneconomic* nature, of gender-based violence that scotched the aggregation principle in *Morrison*.) Because wholly intrastate drug possession is no more "economic" or "commercial" than wholly intrastate gun possession, the constitutionality of the CSA's application here must rise or fall here on the existence of a substantial connection between *respondents' own conduct* and interstate commerce. Because the record demonstrates (and we do not take the Government to dispute) that there is none, the Act may not validly be applied to respondents' activities.

B. Even If *Wickard* Were Applicable, It Would Not Justify Application Of The CSA To Respondents' Purely Local Activities.

Even if the aggregation principle were not categorically out of bounds here, *Wickard* – heretofore the high-water mark of Congress' Commerce-Clause authority – would not justify federal regulation of respondents' purely intrastate, personal possession and use of marijuana. Despite superficial similarities, this case is not a *Wickard* redux. The Government's description of

Wickard as a case about a lone farmer's "home-grown production of wheat" (U.S. Br. 37) for his own "personal use" (U.S. Br. 16) is, with respect, an oversimplification. It is just not true that it is "impossible to distinguish the relevant conduct surrounding the cultivation and use of the marijuana crop at issue in this case from the cultivation and use of the wheat crop that affected interstate commerce in" *Wickard*. U.S. Br. 8 (quoting Pet. App. 26a). Understanding why not – and, correlatively, why the Government's argument would carry the Court well beyond *Wickard* and into uncharted Commerce-Clause waters – requires a fuller understanding of the economic and agricultural facts underlying *Wickard* than the Government's brief provides.

As noted, the aggregation principle, as announced in *Wickard* and as reiterated in subsequent cases, permits a reviewing court to consider the effect on interstate commerce of an individual litigant's conduct "taken together with that of many others similarly situated." *Wickard*, 317 U.S. at 127-28. Accordingly, the first order of business in understanding aggregation is discerning what, exactly, Roscoe Filburn was doing on his farm such that his conduct, when "taken together with that of many others similarly situated" to him, would substantially affect interstate commerce.

He was *not* just baking bread. There is a persistent myth – to which the Government's brief seems to subscribe – that *Wickard* stands for the proposition that "wheat a farmer bakes into bread and eats at home is part of 'interstate commerce'" subject to congressional regulation. *Village of Oconomowoc Lake v. Dayton Hudson Corp.*, 24 F.3d 962, 965 (7th Cir. 1994). The myth is just that: a myth – an urban (or rural, as the case may be) legend. As one scholar has noted, "Farmer Filburn was not an organic home baker who had decided to raise wheat for a few loaves of bread"; rather, he "raised wheat commercially and regularly sold a portion" of his crop on the open market. Deborah Jones Merritt, *Commerce!*, 94 Mich. L. Rev. 674, 748-49 (1995). Indeed, the math shows

that "[t]o consume the 239 excess bushels at issue in the July 1941 wheat harvest, the Filburns would have had to consume nearly forty-four one-pound loaves of bread each day for the following year." Jim Chen, *Filburn's Legacy*, 52 Emory L.J. 1719, 1759 (2003).

Far from organic home baker, Roscoe Filburn owned and operated a large and multifaceted farming operation. As to scope, this Court's opinion reflects that Filburn's annual "wheat acreage allotment" under the Agricultural Adjustment Act ("AAA") was 11.1 acres, at a normal yield of 20.1 bushels of wheat per acre, for a total of more than 223 bushels. 317 U.S. at 114. Filburn planted an additional 11.9 acres and harvested an additional 239 bushels, bringing his total harvest to 462 bushels (or 27,720 pounds) of wheat. *Id.* Notably, the marketing quota at issue in *Wickard* applied only to large farms; it expressly exempted "any farm on which the normal production of the acreage planted to wheat was less than 200 bushels." *Id.* at 130 n.30. Plainly, then, Filburn was no small player. Had he been the organic baker of legend, his case never would have arisen; Congress had not even attempted to extend its regulatory reach to activities so local in character.

With respect to the nature of Mr. Filburn's operation, this Court's opinion in *Wickard* recites that Filburn disposed of his wheat crop in four different ways: (i) he sold some at market; (ii) he fed part to "poultry and livestock on the farm, some which [was then] sold"; (iii) he used some to make flour for bread for his family; and (iv) he kept some for seeding the following year's crop. *Id.* at 114. The question in *Wickard* was whether the Commerce Clause authorized the Federal Government to regulate the portion of Mr. Filburn's wheat yield used "for consumption on the farm." *Id.* at 118.

But, again, to be clear, the case was not principally about the wheat Mr. Filburn used to feed his family; were that the only use that Filburn had made of his wheat, his farm would have fallen outside the AAA's ambit entirely. Thus, the term "home consumption," as used in *Wickard*

(and as repeated by the Government here, *see* U.S. Br. 15), "does not refer primarily to bread and pies baked by wheat growers." Merritt, *supra*, at 749. "Instead, most farm consumption of wheat [was] devoted to feeding livestock who [were] then sold commercially and to reseeding fields to produce more wheat for commercial sale." *Id.* The statistics that the Government reported to this Court in *Wickard* tell the story. For the years 1931-1936, average U.S. wheat production was 680,603,000 bushels. The average distribution of the wheat produced in those years was as follows:

Sold on the market	484,673,000 bushels (71.2%)
Fed to livestock on the farm	107,608,000 bushels (15.8%)
Used as seed on the farm	72,567,000 bushels (10.7%)
Used in the household	15,755,000 bushels (2.3%)

See Br. for Appellants at 12, *in* 39 *Landmark Briefs and Arguments of the Supreme Court of the United States: Constitutional Law* 677, 692 (P. Kurland & G. Casper eds., 1975). According to another estimate based on government calculations, "[i]n Filburn's time, farmers fed twenty times more wheat to livestock than they ground into flour for home use." Chen, *supra*, at 1759 (citing U.S. Dep't of Agric., Field and Seed Crops by States, 1949-54, at 8 (1957) (Stat. Bull. No. 208)). In any event, the basic point, as summarized by the Government in its brief in *Wickard*, was that "a substantial quantity of wheat [was] consumed on the farm as feed for livestock, as seed, *and, to a slight extent, as food.*" Br. for Appellants at 41, *in Landmark Briefs*, *supra*, at 721 (emphasis added).

In addition to sheer "volume," Congress and the *Wickard* Court were concerned about "variability" in the wheat market. 317 U.S. at 128. Specifically, the Court emphasized that the "effect of consumption of homegrown wheat on interstate commerce is due to the fact that it

constitutes the most variable factor in the disappearance of the wheat crop." *Id.* at 127. But while overall "[c]onsumption on the farm where grown appear[ed] to vary in an amount greater than 20 per cent of average production," the Court noted that the "total amount of wheat consumed as food varies but relatively little, and use as seed is relatively constant." *Id.* Implicit in the Court's summary is the fact that the variability in home-consumed wheat resulted primarily from a single source: the on-farm use of wheat as feed for poultry and livestock. The Government's brief to the Court made the point explicit: While the "human consumption" of wheat was "subject to less variation than that of most commodities" and the amount of wheat "used for seed [was] also fairly constant," the amount "used for livestock feed fluctuate[d] widely with changes in livestock prices and in the relation between the prices of alternative feeds and the price of wheat." Br. for Appellant at 15, *in Landmark Briefs, supra*, at 695. Statistics confirm the Government's point. During the years preceding the AAA amendment at issue in *Wickard*, on-farm uses of wheat had varied as follows:

Fed to livestock on the farm	28-174 million bushels (521% variation)
Used as seed on the farm	73-97 million bushels (33% variation)
Used in the household	10-16 million bushels (6% variation)

Robert L. Stern, *The Commerce Clause and the National Economy, 1933-1946: Part II*, 59 Harv. L. Rev. 883, 902 (1946); *accord* Br. for Appellants at 12-13, *in Landmark Briefs, supra*, at 692-93.

Accordingly, when, following the Government's lead, the *Wickard* Court emphasized that it could "hardly be denied" that a factor of such "volume and variability" as "home-consumed wheat" would have a substantial

influence on interstate market conditions, 317 U.S. at 129, the home consumption with which it was principally concerned was the use of wheat as feed for poultry and livestock – which, of course, farmers would then turn around and sell at market. As a result of wheat farmers' decisions "to keep the crop for on-farm use as animal feed," a sizeable "portion of the wheat crop was [being] converted into meat, poultry, milk, or eggs." Chen, *supra*, at 1758. This practice of "[t]ransforming a field crop into grocery staples require[d] nothing more mysterious than the feeding of farm animals," whose products could then be sold – free of regulations on wheat – on the open market. *Id.* at 1760. "By converting excess wheat into milk, meat, poultry, and eggs, the Filburn farm engaged in a time-honored practice of regulated firms: manipulating investments between a regulated line of business (wheat) and nonregulated lines (meat, dairy, poultry, and eggs)." *Id.* Congress' fundamental purpose in extending the AAA beyond wheat actually sold at market to reach all wheat produced on farms was to prevent farmers from defeating wheat-marketing quotas "by redirecting wheat to the feeding bin." *Id.* at 1758.

Why is all of this important? For two reasons. First, because, as noted above, *Wickard*'s aggregation principle requires a precise understanding of an individual litigant's conduct – specifically, for the purpose of determining the class of persons who are "similarly situated" to him, 317 U.S. at 127-28, and whose conduct, therefore, may properly be aggregated in assessing interstate effects. *See Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*, 531 U.S. 159, 173 (2001) (court must "evaluate the precise object or activity that, in the aggregate, substantially affects interstate commerce"). And second, because *Wickard* is "the most far reaching example of Commerce Clause authority over intrastate activity," *Lopez*, 514 U.S. at 560, and because a comparison of that case with this shows that the Government is now asking this Court to take a quantum leap beyond *Wickard*.

Roscoe Filburn was *not*, as legend would have it, a simple farmer raising wheat to feed his family; rather, like other wheat farmers of his day, Filburn sold the great majority of his wheat commercially, either directly (on the open wheat market) or indirectly (for instance, in the form of wheat-fed livestock and poultry). Without conceding the initial correctness of *Wickard*, it is easy to see that, when "taken together," all of the Nation's Roscoe Filburns – *i.e.*, farmers who, like Filburn himself, used their acreage primarily for market purposes – likely generated a substantial effect on interstate commerce. Respondents here (and, importantly for aggregation purposes, those "similarly situated" to them) are in a very different boat: "They do not sell, barter, or exchange cannabis, or use it to produce any other product that they sell, barter, or exchange." Br. in Opp. 15. Put simply, *respondents are not market actors*. Respondents' simple possession of marijuana for personal use is akin to Roscoe Filburn's use – considered in isolation – of wheat to bake bread to feed his family. Had *Wickard* really been just about Filburn's bread-baking, it is inconceivable to us that the case would have come out the same way.

C. To The Extent That *Wickard* Can Be Read To Justify Federal Regulation Of Respondents' Local Activities, It Should Be Overruled.

If *Wickard* is properly read (as we submit it is not) to permit direct federal regulation of respondents' purely local, personal possession of marijuana – the equivalent of Roscoe Filburn's bread-baking, considered in isolation – it should be overruled. If, as the Government suggests, *Wickard* establishes that any activity "occurring within a market is subject to Congress's commerce power even when the activity may itself not be commercial" (Pet. at 10), then it is unquestionably true that the aggregation principle knows "no stopping point," *Lopez*, 514 U.S. at 600 (Thomas, J., concurring), and should be abandoned as a rule of constitutional law.

The Government's rationale would sanction federal regulation not only of "simple drug possession" – and gun possession, *but see Lopez* – but of a whole host of other local activities, as well. As just one example, consider that this Court has recognized that there exists a commercial "market" for garbage. *See C&A Carbone, Inc. v. Clarkstowne*, 511 U.S. 383, 391 (1994); *City of Philadelphia v. New Jersey*, 437 U.S. 617, 621-23 (1978). Accordingly, on the Government's reading of *Wickard*, Congress (or HHS, or HUD, or EPA) could commandeer the regulation of local litter. That cannot be the law. *See Lopez*, 514 U.S. at 585 (Thomas, J., concurring). The Government's theory of *Wickard* would give to Congress the very "plenary police power" that the Constitution "withhold[s]" from it, *id.* at 566 (majority opinion), and would thus "obliterate the distinction between what is national and what is local" and tend to "create a completely centralized government," *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37 (1937).

III. The Government's "Frustration Of Purpose" Argument Does Not Justify The CSA's Application To Purely Local Activity.

The Government devotes a substantial portion of its defense of the CSA's application here to the argument that its ability to police the interstate aspects of the drug trade will be undercut if it cannot also regulate purely local possession and personal use. *See* U.S. Br. 20-35. For one thing, the Government contends that Congress ought to be able to get at the local possession and use that, it says, "feeds" the larger illicit drug market. U.S. Br. 27. To a similar end, the Government argues that "given the fungible nature of drugs," it is "'not feasible to distinguish'" between drugs cultivated, possessed, and used locally from those moving in interstate commerce "'in terms of controls.'" U.S. Br. 29 (quoting 21 U.S.C. §801(5)); *see also id.* at 30 ("difficulties of proof"). Thus, the Government says (with emphasis), "Congress concluded that '*[f]ederal control of the intrastate incidents*

of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.'" U.S. Br. 23 (quoting 21 U.S.C. §801(6)); *accord id.* at 11 ("Congress has concluded that regulation of all intrastate drug activity '*is essential* to the effective control' of interstate drug trafficking." (Government's emphasis)).

There are several problems with the Government's frustration-of-purpose argument. First, the Government's argument assumes – wrongly, *see supra* at 17-18 – that *Wickard*'s aggregation principle applies here. There is no dispute that the respondents *in this case* cultivate, possess, and consume the marijuana at issue entirely within the State of California. Accordingly, there is no problem *in this case* of distinguishing intra- from interstate marijuana, nor is there any reason on the record here to think that the marijuana *in this case* is somehow "feed[ing]" the larger interstate drug market. *See, e.g.*, U.S. Br. 9 (quoting district court's preliminary injunction in this case as reaching only "intrastate, non-commercial cultivation, possession, and use" of marijuana "which is not used for distribution, sale, or exchange"). Assuming that the enforcement concerns the Government identifies exist, they exist on a macro level, not in this case specifically. And because the aggregation principle does not apply here (drug possession not being an "economic" activity), the "feed[ing]" and "fungib[ility]" premises underlying the CSA's application to intrastate activity melt away.

Second, the Government's frustration-of-purpose argument – that without authority over local cultivation and possession Congress cannot efficiently regulate interstate trafficking – is not (nor does it really even purport to be) a *constitutional* argument. At bottom, the Government's contention seems to be that a loss of control over local activity would undercut the "effectiveness of the comprehensive regulatory regime Congress established" and "interfere with Congress's objectives" (U.S. Br. 12-13), and that, accordingly, "the CSA comprehensively bans *all* manufacture, distribution, and possession of any

scheduled drug" (U.S. Br. 17). But this is not a run-of-the-mill statutory construction case in which invocations of congressional purpose or arguments about effective enforcement can carry the day. Rather, the question presented here is whether the regime that "Congress established" comports with the Constitution and whether the CSA *may* validly control "all" aspects – including purely local aspects – of marijuana cultivation, possession, and use.

On that score, this Court has emphasized in numerous contexts before that the "prospect of additional administrative inconvenience has not been thought to justify invasion of fundamental constitutional rights." *Carey v. Population Servs. Int'l*, 431 U.S. 678, 691 (1977); *accord, e.g., City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 508 (1989); *Tashjian v. Republican Party of Conn.*, 479 U.S. 208, 218 (1986); *Craig v. Boren*, 429 U.S. 190, 198 (1976). In the context of criminal law enforcement specifically, there are, of course, all sorts of crime-fighting techniques – general searches, coerced confessions, and the like – that, despite their obvious effectiveness, are simply off-limits. Indeed, one need look no further than the line of cases beginning with *Apprendi v. New Jersey*, 530 U.S. 466 (2000), and proceeding through *Ring v. Arizona*, 536 U.S. 584 (2002), and *Blakely v. Washington*, 124 S. Ct. 2531 (2004) – and perhaps culminating in *United States v. Booker*, No. 04-104, and *United States v. Fanfan*, No. 04-105 – to appreciate that not even the threat of something much more serious than administrative inefficiency can suffice to justify dispensing with constitutional protections. There is no reason why arguments from convenience or feasibility, deemed insufficient when dealing with individual rights, ought to hold sway here given that our federalist structure of government, like the Bill of Rights itself, "'was adopted by the Framers to ensure protection of our fundamental liberties.'" *Lopez*, 514 U.S. at 552 (quoting *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991)).

Third, although the Government has asserted that "comprehensive regulation of ... local activity is essential to effectuate control of the interstate drug market" (U.S. Br. 24), and that the CSA's objectives "cannot be achieved" without control over intrastate conduct (Pet. at 14), it has offered no hard data to substantiate those assertions. In support of its contention that it needs to be able to reach purely local activity to effectuate the CSA's "central purposes" (U.S. Br. 17), the Government relies principally on rote recitations of congressional findings (U.S. Br. 11, 22-23, 29) and asserts that "[t]hose findings fully support Congress's conclusions" concerning the necessity of regulating local activity (U.S. Br. 23-24). The problem, respectfully, is that while the "findings" may support the "conclusions," the Government has offered nothing in the way of evidence to support the findings. While the Government offers some data in its brief (the accuracy of which we do not doubt for a moment) concerning the scope of the marijuana problem generally (U.S. Br. 18-20), nowhere does it provide any evidence – statistical, anecdotal, or otherwise – that federal drug policy cannot survive without preemptive regulatory authority over purely local activity. In place of analysis, the Government merely asserts that the risk is "obvious" (U.S. Br. 25) and "comports with common sense" (U.S. Br. 29). We respectfully submit that where the Federal Government is so clearly pushing the constitutional envelope – here, a full step beyond *Wickard*, *see supra* at 18-24 – it must, at the very least, make a more sustained showing than it has here.

Fourth – and the capper from the our perspective – the Government's arguments about the imperative of effective drug-control policy *completely ignore the ongoing efforts of state and local law enforcement.* For instance, in connection with its contention that local use and possession feed demand and thus swell the interstate market, the Government says that "[i]f *Congress* lacked the power to regulate" intrastate cultivation and possession, "the market effects on the demand and supply

of marijuana would likely be enormous," and, indeed, that "[t]he risk that both the supply and demand could dramatically increase were home-grown marijuana beyond the reach of *federal law* is obvious." U.S. Br. 25 (emphasis added). The Government later reiterates its position that "the unregulated intrastate manufacturing, possession, and distribution of a drug" would frustrate efforts to stem interstate trafficking, and that "[w]ere *Congress* to lack the power to regulate" local activity, persons could function essentially as "unregulated and unsupervised" drug manufacturers and pharmacies. U.S. Br. 32, 33-34.

Where do States, counties, and municipalities fit into the Government's theory of this case? Regrettably, the answer appears to be that they don't. The Government's assertion of federal power over local activity seems rather plainly to rest on the assumption that absent federal regulation, anarchy would reign at the local level. The Government's assumption of local law enforcement's irrelevance is (to say the least) unwarranted. As Alabama's own record of enforcement makes clear, *see supra* at 5-7, the States are ready, willing, and able to police and prosecute local drug crimes. *See also Riley v. National Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988) ("[W]e presume that [state] law enforcement officers are ready and able to enforce" the law.). And the Government has done nothing in its brief to demonstrate (nor could it, we submit) that state and local enforcement efforts are so woefully inadequate – or a cooperative relationship with state and local governments so unduly burdensome – that a federal takeover is justified.

* * *

None of this is to suggest, of course, that the States don't want and need the Federal Government's help. The amici States certainly do – subject to constitutional limits. Fortunately, there are viable crime-fighting alternatives short of a full-blown federal takeover of local policing. The Federal Government, for instance, grants money to

state and local law-enforcement agencies – for which those agencies are grateful, we can attest – aimed at preventing and eradicating marijuana use. *See, e.g.*, Office of National Drug Control Policy, Drug Policy Information Clearinghouse: State of Alabama 2-4 (May 2004) ("ONDCP Report") (cataloguing Alabama programs receiving "[f]ederal [f]unding"). It is the Federal Government's prerogative, within limits, to attach conditions to the use of those funds and to direct expenditures toward what it perceives to be the most effective drug-control and prevention strategies. *See, e.g.*, *Sabri v. United States*, 124 S. Ct. 1941, 1947 (2004); *South Dakota v. Dole*, 483 U.S. 203, 206 (1987). Furthermore, so long as it does not cross the line into unconstitutional "commandeering," *see Printz v. United States*, 521 U.S. 898 (1997), the Federal Government may – and we submit should – partner with state and local law enforcement to achieve the comprehensive regulation of the drug trade that all agree is needed. *See, e.g.*, ONDCP Report, *supra*, at 7 ("cooperative program between DEA and its state and local law enforcement counterparts"); Birmingham PD Report, *supra* at 5 ("interagency cooperation" with federal authorities). What the Federal Government may *not* do is displace the States from their traditional role as the enforcers of local criminal law and assume the States' historic police power to provide for the health, safety, welfare, and morals of their citizens.

CONCLUSION

This is an extraordinary case. The amici States find themselves, essentially, in complete agreement with the Federal Government as a matter of drug-control policy, but in complete disagreement as a matter of constitutional principle. Bound through their elected officials to privilege the latter over the former, *see, e.g.*, Ala. Const. Art. XVI, §279 ("[o]ath of office"), the amici States respectfully submit that the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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APPENDIX A

State Marijuana-Possession Prohibitions

State	Statute
Alabama	Ala. Code §§ 13A-12-213, 13A-12-214
Alaska	Alaska Stat. § 11.71.060(a) (held unconstitutional by *Noy v. State*, 83 P.3d 545 (Alaska Ct. App. 2003))
Arizona	Ariz. Rev. Stat. § 13-3405
Arkansas	Ark. Code Ann. § 5-64-401
California	Cal. Health & Safety Code § 11357
Colorado	Colo. Rev. Stat. Ann. § 18-18-405
Connecticut	Conn. Gen. Stat. § 21a-279
Delaware	Del. Code Ann. tit. 16, § 4754(a)
District of Columbia	D.C. Code Ann. § 48-904.01
Florida	Fla. Stat. Ann. § 893.13
Georgia	Ga. Code Ann. § 16-13-30
Hawaii	Haw. Rev. Stat. § 712-1249
Idaho	Idaho Code § 37-2732
Illinois	720 Ill. Comp. Stat. 550/4
Indiana	Ind. Code § 35-48-4-11
Iowa	Iowa Code Ann. § 124.401
Kansas	Kan. Stat. Ann. § 65-4162(a)(3)
Kentucky	Ky. Rev. Stat. Ann. § 218A.500(2)
Louisiana	La. Rev. Stat. Ann. § 40:966(C)
Maine	Me. Rev. Stat. Ann. tit. 22 § 2383

State	Statute
Maryland	Md. Code Ann., Crim. Law § 5-601
Massachusetts	Mass. Gen. Laws Ann. ch. 94c, § 34
Michigan	Mich. Comp. Laws § 333.7403(2)(d)
Minnesota	Minn. Stat. Ann. § 152.025
Mississippi	Miss. Code Ann. § 41-29-139(c)
Missouri	Mo. Ann. Stat. § 195.223
Montana	Mont. Code Ann. § 45-9-102(2)
Nebraska	Neb. Rev. Stat. § 28-416
Nevada	Nev. Rev. Stat. 453.336
New Hampshire	N.H. Rev. Stat. Ann. § 318-B:2
New Jersey	N.J. Stat. Ann. § 2c:35-10a(3)
New Mexico	N.M. Stat. Ann. § 30-31-23
New York	New York Penal Law § 221.05
North Carolina	N.C. Gen. Stat. § 90-95(a)(3)
North Dakota	N.D. Cent. Code § 19-03.1-23(6)
Ohio	Ohio Rev. Code Ann. § 2925.11
Oklahoma	Okla. Stat. Ann. tit. 63 § 2-402
Oregon	Or. Rev. Stat. § 475.992(4)
Pennsylvania	Pa. Stat. Ann. tit. 35 § 780-113
Rhode Island	R.I. Gen. Laws § 21-28-4.01
South Carolina	S.C. Code Ann. § 44-53-370
South Dakota	S.D. Codified Laws § 22-42-6
Tennessee	Tenn. Code Ann. § 39-17-417

State	Statute
Texas	Tex. Health & Safety Code Ann. § 481.115
Utah	Utah Code Ann. § 58-37-8
Vermont	Vt. Stat. Ann. tit. 18 § 4230(a)(1)
Virginia	Va. Code Ann. § 182-250.1
Washington	Wash. Rev. Code Ann. § 69.50.4013
West Virginia	W. Va. Code § 60A-4-401
Wisconsin	Wis. Stat. Ann. § 961.41(3g)(e)
Wyoming	Wyo. Stat. Ann. § 35-7-1031

ORAL ARGUMENT

No. 03-1454

Supreme Court, U.S.
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In The Supreme Court of the United States

JOHN ASHCROFT, Attorney General, et al.,

Petitioners,

v.

ANGEL McCLARY RAICH, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

AMICUS CURIAE BRIEF OF THE STATES OF CALIFORNIA, MARYLAND, AND WASHINGTON IN SUPPORT OF ANGEL McCLARY RAICH, ET AL.

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, properly applies under the Commerce Clause to state regulated noncommercial intrastate manufacture, possession, distribution, and use of marijuana for personal medicinal purposes under a physician's supervision.

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STATEMENT OF INTEREST

Amici Curiae States, like their sisters who have joined Alabama as amici curiae in support of respondents, believe that the Government exceeds its constitutional authority by enforcing the Controlled Substances Act (CSA), Pub.L. 91-513, 21 U.S.C. § 801, et seq., against possession of marijuana for regulated personal, medicinal use as authorized by California's Compassionate Use Act of 1996, Cal. Health & Safety Code, § 11362.5. Amici write separately, however, to emphasize that a State's policy choice to permit limited, medicinal usage of marijuana for compassionate ends may co-exist with the State's continued, vigorous enforcement of laws prohibiting *illicit* marijuana possession and trafficking consistent with the congressional purposes reflected in the CSA. Amici also write separately to emphasize that Congress, in enacting the CSA, did not purport to preclude State's from regulating wholly local, personal medicinal use of marijuana.

ARGUMENT

A. California's Compassionate Use Act Was Enacted in Exercise of California's Historic Police Powers, in Response to an Identified Need, and in Furtherance of a Constitutionally Permissible Purpose

In 1970, when the Controlled Substances Act (CSA), 21 U.S.C. § 801 et seq., was passed, the ravages of AIDS were unknown. By 1996, the year California enacted California's Compassionate Use Act of 1996, Cal. Health & Safety Code, § 11362.5 (Proposition 215), the AIDS epidemic had been revealed as one of the most horrific diseases in history, killing millions of people throughout the

world, becoming the eighth leading cause of death in the United States alone. *CDC Media Relations: HHS News,* Oct. 7, 1998. It was against this background, and presented with solid evidence that marijuana can relieve the suffering of those afflicted by certain types of illness, including glaucoma, multiple sclerosis, spasticity, severe pain, and nausea induced by the drugs used in chemotherapy and in the treatment of AIDS, that the citizens of California overwhelmingly adopted Proposition 215. *See*, generally, *Marijuana and Medicine: Assessing the Science Base*, National Academy Press 1999. More specifically, as one jurist has noted, evidence indicates that for some, marijuana is the only drug capable of reducing their anguish. *See, e.g., Conant v. Walters*, 309 F.3d 629, 640-641 (9th Cir. 2002) (Kozinski, J., concurring) ("A surprising number of health care professionals and organizations have concluded that the use of marijuana may be appropriate for a small class of patients who do not respond well to, or do not tolerate, available prescription drugs.").[1] Eleven states now authorize the use of cannabis by seriously ill people.[2]

[1] The development and use of Marinol, the trade name for a product containing synthetic tetrahydrocannabinol (THC), a psychoactive ingredient in marijuana, further belies the contention that cannabis *presently* has no accepted medical use. "Dronabinol, the active ingredient in Marinol, is synthetic delta-9-tetrahydrocannabinol (delta-9-THC). Delta-9-tetrahydrocannabinol is also a naturally occurring component of *Cannabis sativa L.* (Marijuana)." *Physicians Desk Reference* 55th ed. 2001, page 2828. Although the outer parameters of it may benefit from further clarification, they include " . . . treatment of: 1. anorexia associated with weight loss in patients with AIDS; and 2. nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments." *PDR* 55th ed. 2001, page 2829.

[2] Alaska, Ballot Measure #8 on November 3, 1998 Alaska Statutes, title 17, Chapter 37, § 17.37.010 et seq.; Arizona, Proposition 200, November 5, 1996, title 13, chapter 13,

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In our federal system States often serve as democracy's laboratories, trying out new, or innovative solutions to society's ills. *Washington v. Glucksberg* 521 U.S. 702, 737 (1997) (O'Connor, J., concurring); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting.) "The essence of federalism is that the state must be free to develop a variety of solutions to problems and not be forced into a common, uniform mold." *Addington v. Texas*, 441 U.S. 418, 431 (1979). The Framers recognized from the very inception of the Republic that a federal government might find it hard to resist the temptation to overbear the interests of the States. They provided the means for diminishing that risk by imposing limitations on the federal government's power. As this Court has noted:

> [T]he Constitution of the United States . . . recognizes and preserves the autonomy and independence of the States – independence in their legislative and independence in their judicial departments. Supervision over either the legislative or the judicial action of the Satates is in no case permissible except as to matters by the Constitution specifically authorized or delegated to

A.R.S. § 13-3412.01; Colorado, Amendment 20, November 7, 2000, Co. Const. Art. 18, § 14; Hawaii, Senate Bill 862, June 14, 2000, took effect December 28, 2000, HI Statutes, D. 1, T. 19, Ch. 329, Pt. IX, §§ 329-121 et seq.; Louisiana, LSA-R.S. 40:1021, 40:1034; Maine, Question 2, November 2, 1999, took effect December 22, 1999, ME ST T. 15 § 5821-A; Maryland, MD Code, Criminal Law, § 5-601 (defense of medical necessity); Nevada, Question 9, November 7, 2000, took effect October 1, 2001, NV Statutes, T. 40, Ch. 453A, §§ 453A.010-453A.170, inclusive; Oregon, Measure 67, November 3, 1998, took effect on December 3, 1998, OR ST T. 37, Ch. 475, Prec. 475.300 et seq.; Vermont, Senate Bill 76, May 26, 2004; Washington, Measure 692, November 3, 1998, WA ST 69.51A.005.

> the United States. Any interference with either, except as thus permitted, is an invasion of the authority of the State and, to that extent, a denial of its independence.

Alden v. Maine, 527 U.S. 706, 754 (1999), quoting *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938).

B. Congress Did Not Intend the CSA to Be Used to Preclude Wholly Local, Medicinal Usage of Marijuana Subject to State-regulated Medical Supervision.

On its face, the CSA does not purport to regulate medical usage of marijuana. Indeed, in 1970, as Congress found, marijuana had "no currently accepted medical use in treatment in the United States," and there was "a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b)(1). These legislative findings must be understood in the context of their time. The word "currently" suggests not a broad, medical absolute, but recognition that the future may provide other information bearing on that description. Congress's findings properly address the integrated interstate trade in *illicit* drugs. As Senator Dodd said at the time of its enactment "[It] cannot be overemphasized that the . . . [CSA] is designed to crackdown hard on the narcotics pusher and the illegal diverters of pep pills and goof balls." 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970). The findings are completely silent regarding lawfully enacted, state authorized, intrastate cultivation, distribution, possession and use of medicinal cannabis.

The CSA, therefore, cannot reasonably be read to evince a congressional intent to preclude *state regulated* medical cultivation and usage of Schedule 1 drugs – provided, at least, that the activity is wholly local in scope – should the relevant science evolve and states determine that such drugs are not only medically useful but may safely be used under medical supervision. In the absence of clear statement to that effect, courts will not presume that Congress intended to exclude States from the exercise of their historic police powers. *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947); *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996); *see also, Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.,* 519 U.S. 316, 325 (1997) ("[W]here federal law is said to bar state action in fields of traditional state regulation, . . . [courts] have worked on the assumption that the historic police powers of the States were not to be superceded by the Federal Act unless that was the clear and manifest purpose of Congress."). In any event, Congress made clear its intent *not* to preempt the field of regulating marijuana usage to the exclusion of the States, "unless there is a positive conflict between [the] subchapter and that State law so that the two cannot consistently stand together." 21 U.S.C. § 903. No such "positive conflict" exists when, as here, the state-regulated possession is wholly local in its scope and effect.

Amici submit that possession of marijuana for bona fide medicinal purposes, subject to state-regulated physician recommendation and oversight, is not the sort of possession contemplated by Congress in enacting the CSA. Congress made no findings regarding state regulated medical usage of Schedule 1 drugs, because such an activity did not exist in 1970. There was, therefore, no

evidence upon which Congress might have based a finding that local, state-regulated medicinal usage of marijuana (or any other Schedule 1 drug) affects interstate commerce. In the absence of any evidence whatsoever concerning state-regulated medicinal usage of marijuana, the CSA cannot reasonably be construed to reflect Congress' belief that such state-regulated usage affects interstate commerce. *Cf.*, *Alabama v. Garrett,* 531 U.S. 356, 369-70 (2001) (noting absence of evidence of state violations to support exercise of congressional power under section 5 of the Fourteenth Amendment).

C. To Construe the CSA as Precluding Even State-regulated Possession of Marijuana for Medicinal Purposes Would Render the Statute Unconstitutional as Applied under the Tenth Amendment, Especially in View of the Lack of Congressional Findings Regarding Such Usage.

The federal government has limited authority to interfere with State legislation enacted for the protection of citizen health, safety, and welfare. "The [Tenth] Amendment expressly declares the constitutional policy that Congress may not exercise power in a fashion that impairs the States' integrity, or their ability to function effectively in a federal system. . . . " *Fry v. United States*, 421 U.S. 542, 547, Fn. 7 (1975). And it cannot reasonably be doubted the regulation of health and safety matters is primarily and historically a matter of state concern. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) ("Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens"); *see also*, *Hillsborough County v. Automated Medical Lab. Inc.*, 471 U.S. 707, 719, 105 (1985) ("the

regulation of health and safety matters is primarily and historically a matter of state concern"); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons").

As noted above, Congress itself never purported to divest the States of their police power to regulate wholly local usage of marijuana for medicinal purposes. But the Executive Branch's determination to pursue criminal prosecutions of persons availing themselves of the protections granted under California's law, "alter[s] the 'usual constitutional balance between the States and the Federal Government.'" *Cf., Gregory v. Ashcroft,* 501 U.S. 452, 561 (1991), quoting *Atascadero State Hosp. v. Scanlon,* 473 U.S. 234, 242 (1985) ("'[I]f Congress intends to alter the "usual constitutional balance between the States and the Federal Government," it must make its intention to do so "unmistakably clear in the language of the statute."'").

Congress' powers under the Commerce Clause are not unlimited. For example, absent a demonstrable nexus to interstate commerce, Congress may not ban the possession of a weapon within a prescribed distance of a school, *United States v. Lopez*, 514 U.S. 549 (1995), impose civil remedies for gender-based violence, *United States v. Morrison*, 529 U.S. 598 (2000), or may it make mere possession of a firearm by an ex-felon a federal crime, *United States v. Bass*, 404 U.S. 336 (1971). Generally, Congress may regulate three categories of activity under its commerce power: (1) it may regulate the use of the *channels* of interstate commerce, (2) it may regulate and protect the *instrumentalities* of interstate commerce and finally, (3) it

may regulate those activities having a *substantial relation* to interstate commerce. *See Lopez*, 514 U.S. at 552.

To satisfy the Tenth Amendment, then, application of the Controlled Substances Act must be restricted to the regulation of activities employing the channels and instrumentalities of, and having a substantial relationship to, interstate commerce. These foundational jurisdictional elements are present with respect to the illicit interstate drug trade; they are missing with respect to the activity regulated by California's Compassionate Use Act, which is wholly *intra*-state.

Amici acknowledge that the CSA recites: "Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce." 21 U.S.C. § 801(3). However, by its own terms, this Congressional finding relates to the *trafficking* of illicit drugs, not regulated personal medical usage.[3]

The United States argues that "intrastate drug distribution and use are subject to congressional regulation because Congress rationally determined that such activities as a class substantially affect the marijuana market as a whole." (Br. of the U.S. at 20). The assertion lacks merit. The CSA antedates the Compassionate Use Act and state-regulated medical usage by more than a

[3] Furthermore, Congress was manifestly concerned with "*illegal*" possession of controlled substances, *see* 21 U.S.C. § 801(2), not with state-regulated *lawful* possession for medicinal purposes. By its terms, California's act precludes construction of the statute to authorize "diversion of marijuana for nonmedical purposes." Cal. Health & Safety Code, § 11362.5(b)(2).

quarter century. Congress could not have determined that state-regulated, personal medicinal marijuana usage had an effect on the interstate marijuana trafficking as a whole, because there was no state-regulated medical marijuana program in existence at the time. Moreover, Congress in 1970 would have had no way to assess the beneficial effect that continued state enforcement of state laws prohibiting *illicit* drug use has on ensuring that personal medicinal usage does not "swell[ ]the interstate traffic" in marijuana. *See* 21 U.S.C. § 801(4).[4] There are two separate and distinct classes of intrastate activity having to do with marijuana. One, the classic illicit drug trade, unquestionably is an incident of the otherwise wholly unlawful *interstate* commerce in marijuana, is consistent with the Congress's findings. The other is an entirely separate class of activity expressly authorized by the state of California. It is entirely confined to the regulated *intrastate* cultivation and use of marijuana for the limited medical purpose permitted by Proposition 215 and was not within the contemplation of Congress when the CSA was enacted.

[4] For example, California's Department of Justice, Bureau of Narcotics Enforcement (BNE) operates the "Campaign Against Marijuana Planting" (CAMP), an aggressive marijuana interdiction and eradication effort. CAMP was established in 1983 under the direction of the Attorney General and BNE. This multi-agency law enforcement task force provides personnel to remove marijuana growing operations and promote public information and education on marijuana. Member agencies, comprising local, state and federal law enforcement representatives, carry out the enforcement operations of this program. In 2004 alone, as of September 9, CAMP had seized and destroyed 471,128 plants worth an estimated $1.88 billion. http://caag.state.ca.us/newsalerts/2004/04-103.htm; *see also*, generally, http://caag.state.ca.us/bne/content/camp1.htm.

Amici respectfully submit that the Executive Branch's naked assertion that wholly local, state-regulated personal medicinal marijuana usage affects interstate commerce does not make it so. *Cf.*, *Lopez*, 514 U.S. at 557 n. 2, quoting *Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U.S. 264, 311 (1981) (Rehnquist, J., concurring in judgment) ("[S]imply because Congress may conclude that a particular activity substantially affects interstate commerce does not necessarily make it so.") Congress's findings regarding the scope of the CSA must be interpreted in their proper context. At the time of its enactment no state had instituted a regulated statutory scheme authorizing the medicinal use of marijuana under a physician's care. All trade in marijuana was illicit, but that is no longer the case and the Executive Branch's attempt to cast state authorized medical use in the same light goes beyond the scope of the CSA.

"All great truths begin as blasphemies." *Hoffman v. Cargill*, 142 F.Supp.2d 1117, 1118 (D. Me. 2001), quoting George Bernard Shaw. The question here is whether deference should be paid to California's "heretical" decision to test the medical efficacy of marijuana for the purpose of relieving suffering caused by illness or disease. The Congressional purposes underlying the CSA are not inconsistent with the legitimate state police-power purposes underlying California's Compassionate Use Act; in enacting the former, Congress could not reasonably have intended to preclude the latter.

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

October 13, 2004

Respectfully submitted,

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v.

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On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF *AMICI CURIAE* FOR THE CALIFORNIA NURSES ASSOCIATION AND THE DKT LIBERTY PROJECT IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

The California Nurses Association (CNA) is a professional nursing association of more than 50,000 professional nurses practicing in the State of California. The CNA's primary goals are to promote patient advocacy that protects patients and ensures a single standard of quality healthcare for all. The CNA also seeks to develop the professional and educational advancement of professional nurses, and to foster high standards of nursing practice.

The DKT Liberty Project is a non-profit organization founded to protect the liberties fundamental to a free society. It advocates vigilance over regulation of all kinds, especially restrictions of civil and economic liberties that threaten the reservation of power to the citizenry that underlies our constitutional system.

CNA participated as *amicus curiae* in this case at the Court of Appeals, based on its firm conviction that the District Court's failure to grant a preliminary injunction to protect seriously ill patients whose doctors have recommended cannabis as a last-resort medical treatment seriously infringed upon the constitutional rights of the patients whose well-being both *amici* are committed to preserve. The federal government's actions in this case threatens these (and other) patients' constitutional rights to make autonomous decisions regarding their own bodies, and to seek medical treatment for alleviation of pain and suffering and preservation of life. Likewise, the federal government's actions here attempt to constrain and regulate the purely intrastate practice of medicine, an area historically within the sovereign power of the States. Accordingly, CNA

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[1] This brief is filed with the written consent of both parties, as indicated by letters filed with the Court. No party authored this brief in whole or in part and no one, other than the *amici curiae* or its counsel, monetarily contributed to the preparation or submission of this brief.

and the DKT Liberty Project strongly urge this Court to uphold the Court of Appeals' decision that respects the authority of individual States to exercise their sovereign authority with regard to what medications patients in their states may legally possess and use.

SUMMARY OF ARGUMENT

The history of federal legislation about drugs that Congress believed to be harmful and about pharmaceuticals in interstate commerce demonstrates clearly that the 1970 Controlled Substances Act plowed thoroughly new ground. In attempting to ban the wholly intrastate, non-economic possession and use of cannabis for medical purposes, on the advice and recommendation of a licensed medical practitioner, when the state has authorized such possession and use, Congress has exceeded its enumerated and delegated commerce power.

ARGUMENT

THE FEDERAL POWER TO REGULATE NATIONAL COMMERCE DOES NOT ALLOW CONGRESS TO BAN THE LOCAL, WHOLLY INTRASTATE, NON-ECONOMIC POSSESSION OF CANNABIS FOR MEDICAL PURPOSES SPECIFICALLY ALLOWED BY LOCAL STATE LAW.

While the history of Congress' constitutional authority to "regulate Commerce . . . among the several States," has been largely one of expansion, this Court has recently reiterated one core principle of federalism that limits that authority: "The Constitution requires a distinction between what is truly national and what is truly local." *United States v. Morrison*,

529 U.S. 598, 617-18 (2000); *see also United States v. Lopez*, 514 U.S. 549, 567-68 (1995).

One factor in determining whether a particular activity is local is whether it falls within an area of regulation in which the states are traditionally sovereign. Indeed, in *Lopez*, this Court invalidated a gun-possession statute whose connection to interstate commerce—guns near school threaten education which leads to less productive citizens—would also justify federal statutes "in areas such as criminal law enforcement or education where States historically have been sovereign." *Lopez*, 514 U.S. at 564. Similarly, noting that "we can think of no better example of the police power, which the Founders denied the National Government and reposed in the States, than the suppression of violent crime and vindication of its victims," this Court held that Congress lacked commerce clause authority to prohibit violent crimes based on gender, even when Congress found that such crimes affected interstate commerce. *Morrison*, 529 U.S. at 618.

Here, the Government argues that "neither the purported medical use of marijuana nor the role of a physician in approving it provides the slightest basis for excluding it from the comprehensive coverage of the CSA." Gov't Brief at 41. But, as *Lopez* and *Morrison* teach, the medical context of this case *is critical*, because the activity—intrastate, noncommercial possession of cannabis for medical purposes at a doctor's recommendation—is squarely within the local context of states' reserved powers in the area of public health and welfare. This is so despite the fact that cannabis could be a product in interstate commerce, just as in *Lopez*, a gun could be a product in interstate commerce. A patient's decision, based on her and her doctor's best judgment, to pursue particular medical treatment options to alleviate pain and suffering and to preserve her life, is the opposite of a truly national, and the paradigm of a truly local, indeed, a

private matter. This local medical context, in an area of historical state sovereignty, marks the limits of Congress' interstate commerce authority.[2]

Congress' blanket ban on *any* use, in the face of a state law specifically allowing the medical use at issue here, does in fact obliterate the distinction between what is local and what is truly national. Although Congress has a significant role to play in ensuring that the interstate market for pharmaceuticals insures safe products that are efficacious for their claimed purpose, and that interstate commerce channels are not misused to promote the abuse of dangerous products, Congress cannot appropriate to itself the historical state police power to ban the private, intrastate, non-economic activity of possessing medicine that Congress believes may be harmful but that the State believes to be helpful.

A. Although Congress Has Long Protected Consumers from Adulterated Or Misbranded Drugs In Interstate Commerce, It Has Not Historically Attempted To Prohibit Patients From Possessing Medicine Their Doctors Recommend Or Prescribe.

The history of how Congress has approached the social issue of narcotic and other drug abuse is instructive.[3]

[2] Of course, a state's power to legislate in the area of public health and welfare is not unlimited by any means. It is bounded by constitutional requirements that legislation be, for example, rationally related to *public* health, not discriminatory, and not invasive of its citizens' privacy. *Amici* strongly believe that patients have a fundamental right to make autonomous decisions regarding their own bodies, and to seek medical treatment for alleviating pain and suffering, and to preserve their own lives. Thus, either a state or federal ban on the private, intrastate, non-economic possession of medical cannabis would still be subject to constitutional challenge.

Indeed, some *amici curiae* suggest that this history demonstrates that Congress has been exercising the powers at issue here for nearly a century. Brief of *Amici Curiae* Robert L. DuPont, M.D., *et al.* at 15 ("DuPont *Amici* Brief"). But those *amici* ignore the critical issue of what constitutional powers Congress used and how it used them.

1. Congress Has Long Used Its Interstate Commerce Authority To Protect Consumers Against Unscrupulous Manufacturers.

In 1906, in response to concern about the growing use of "patent" medicines that, unknown to consumers, contained significant quantities of opium, cocaine, and alcohol, Congress enacted the first Pure Food & Drug Act, which required drug manufacturers whose products were in interstate commerce to label those products accurately with the ingredients of the drug. The Act applied, on its face, only to products "introduce[d] into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia." Pure Food Act, Pub. L. No. 59-384, § 2, 34 Stat. 768 (1906).

Consumer protection from manufacturers trying to cut costs was again Congress' goal in the 1938 Food, Drug & Cosmetic Act. That statute was enacted after a manufacturer distributed a new "elixir sulfanilamide" they had tested for flavor and fragrance, but not for safety. More than 75 people died. James T. O'Reilly, *Food and Drug Administration*

[3] As one historian of pharmacy has noted, "[T]here is no better illustration of the encroachment of the power of the federal government into activities that were previously entirely within the province of the states, than what goes on daily behind the prescription counter." David L. Cowan, The Development of State Pharmaceutical Law, 37 Pharmacy in History 49, 56 (1995).

§ 3.04, at 3-13 (2d ed. 1993 & 2004 Supp.) That Act, like the 1906 Act, was enacted under Congress' Commerce Clause authority, and it applied, on its face, only to items in interstate commerce. 21 U.S.C. §§ 321(b), 331(a)-(d) (prohibiting adulteration of drugs while "in interstate commerce," introducing adulterated or misbranded drug "in interstate commerce," and receipt of adulterated or misbranded drugs "in interstate commerce").[4]

Until 1970, Congress continued to tie its regulations related to drugs and medicines to interstate commerce. And even when it stretched in 1965 to suggest it could use its interstate commerce power to reach *intrastate* commerce in some drugs, Congress excepted personal or household use from that law (since personal possession was not "commerce"), and it specifically noted that it was trying to reach the sale of those drugs "when not under the supervision of a licensed practitioner." Drug Control Abuse Amendments of 1965, Pub. L. No. 89-74, § 2, 79 Stat. 226 (1965).

2. *But Congress' Efforts To Prohibit Or Suppress Substances On Public Health Grounds Were Sustained Only Under Congress' Taxing Power.*

From the formation of the union, states—and states alone—were responsible for laws directly regulating the

[4] Nor was this a *pro forma* requirement. In 1946, the FDA seized cartons of spaghetti and macaroni on grounds of adulteration as they sat in a warehouse. But the federal seizure was invalidated because the statute required that the product be adulterated when introduced into, or while in, interstate commerce. *United States v. Phelps Dodge Mercantile Co.*, 157 F.2d 453 (9th Cir. 1946). Where the FDA could only show that the food was adulterated after sitting for two years in a warehouse after traveling in interstate commerce, the case was outside the FDA's jurisdiction. *Id.*

public health and welfare.[5] In the earliest opinion addressing the divergence of federal and state authority, Chief Justice Marshall defined state power as including "that immense mass of legislation, which embraces every thing within the territory of a State, not surrendered to the general government; all of which can be most advantageously exercised by the States themselves. Inspection laws, quarantine laws, health laws of every description . . . are components of this mass." *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824). To the extent public health might justify banning or controlling any substance because of its harmful effects on public health, such a ban would have been clearly within the inherent authority of the states, and outside the limits of federal authority.

Indeed, when Congress first became concerned with the social and public health effects of narcotic drugs at the turn of the 19th century, it acted quite consciously within those widely accepted limits on its delegated power. Rather than assert any authority under the Commerce Clause, Congress enacted the first federal narcotics statute solely under its *taxing* authority. The Harrison Act, enacted in 1914, required registration and payment of an occupational tax of $1.00 per year by all persons who imported, produced, dealt in, sold, or gave away opium, cocaine, or their derivatives. *United States v. Jin Fuey Moy*, 241 U.S. 394, 399-400 (1916). Further, the Act made it unlawful for any unregistered person (except patients with a prescription) who had not paid the tax to possess such products. *Id.*

[5] The early colonists were vigilant. When one Nicholas Knopp sold a "worthless concoction" as a scurvy remedy, the Massachusetts Bay Colony fined him five pounds, and threatened a whipping if the payment were delayed. Wallace F. Janssen, America's First Food and Drug Laws, 30 Food Drug Cosm. L. J. 665, 669 (1975).

When the Act was challenged, as it immediately was, the government tried to argue that "Congress gave [the Act] the appearance of a taxing measure in order to give it a coating of constitutionality, but that it really was a police measure that strained all powers of the legislature, and that [section] 8 means all that it says, taking its words in their plain, literal sense." 241 U.S. at 401. Not surprisingly, the Court rejected that argument and upheld the statute *only* insofar as it was a revenue statute.[6] Although Congress might have a moral end in mind when enacting a revenue statute, the Court held it could accomplish its ends only insofar as they were "within the limits of a revenue measure." *Id.* at 402. Accordingly, the Court held the ban on possession in the tax revenue statute could not apply to a patient, who, not being a seller or a dealer, was not required to register and pay the tax.

In later challenges, the Court continued to uphold the Harrison Act *only* as a revenue-raising measure within Congress' taxing authority:

> In interpreting the [Harrison] A ct, we must assume that it is a taxing measure, for otherwise it would be no law at all. If it is a mere act for the purpose of regulating and restraining the purchase of the opiate and other drugs, it is beyond the power of Congress and must be regarded as invalid.

Nigro v. United States, 276 U.S. 332, 341 (1928); *see also United States v. Doremus*, 249 U.S. 86, 93 (1919) ("[o]f course Congress may not in the exercise of federal power exert authority wholly reserved to the states").

[6] The Court noted that if opium were produced in any state (as opposed being imported through foreign commerce) "obviously the gravest question of power would be raised by an attempt of Congress to make possession of such opium a crime." *Id.* at 401.

And when the government attempted to use the Harrison Act to prosecute doctors for prescribing opiates to particular patients in ways the government disagreed with, the Court strongly rejected that effort. Thus, in *Linder v. United States*, 268 U.S. 5 (1925), the Bureau of Narcotic Affairs—the office at Treasury responsible for enforcing this revenue law—prosecuted a duly registered and tax-paying physician who had given four tablets of morphine and cocaine to a patient who was a known addict, without filing the IRS form. The statute exempted a physician from the form requirement if he distributed the substances directly to the patient "in the course of his professional practice." 268 U.S. at 17. In response to the government's argument that distributing the opiates to an addict was not within the course of the professional practice of medicine, the Court stated unequivocally:

> Obviously, direct control of medical practice in the states is beyond the power of the federal government. Incidental regulation of such practice by Congress through a taxing act cannot extend to matters plainly inappropriate and unnecessary to reasonable enforcement of a revenue measure.

Id. at 18.[7] The Court continued, "Federal power is delegated, and its prescribed limits must not be transcended even though

[7] The Court clarified two earlier cases, *United States v. Doremus*, 249 U.S. 86 (1919) and *Webb v. United States*, 249 U.S. 96 (1919), on which the government relied to argue that doctors could not provide opiates to addicted patients. Noting that in those earlier cases, the facts involved distribution of large amounts of opiates that could be diverted, thus frustrating the revenue purposes of the Act, the Court concluded:

the end seems desirable. . . . [W]e cannot say that by so dispensing [the drugs here] the doctor necessarily transcended the limits of that professional conduct with which Congress never intended to interfere." 268 U.S. at 22-23.

Following its success with the Harrison Act, and alarmed by lurid newspaper accounts of marijuana brought into the country by Mexican laborers, Congress sought to deter non-medical marijuana use by enacting the 1937 Marihuana Tax Act. It did so despite the fact that in the five years preceding that Act, every state had enacted some legislation relating to controlling marijuana, and thirty-five states had enacted some form of the Uniform Narcotic Drug Act, which included an optional provision that would include cannabis in the list of covered narcotics. *See* Richard J. Bonnie & Charles H. Whitebread, II, *The Forbidden Fruit and the Tree of Knowledge: An Inquiry Into the Legal History of American Marijuana Prohibition*, 56 Va. Law. Rev. 971, 1034 (1970).

Like the Harrison Act, the Marijuana Tax Act did *not* prohibit the possession or purchase of cannabis. Rather, as a revenue measure, it required persons importing, producing, selling, or otherwise dealing with cannabis to register with

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> The opinion[s] cannot be accepted as authority for holding that a physician, who acts bona fide and according to fair medical standards, may never give an addict moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction. Enforcement of the tax demands no such drastic rule, *and if the act had such scope it would certainly encounter grave constitutional difficulties*.

Lindner, 268 U.S. at 22 (emphasis added).

the IRS and pay an occupational tax. It also taxed the transfer of cannabis by requiring all transferees of cannabis to file a written order form and to pay a transfer tax of $1.00 per ounce if registered, and $100 per ounce if not registered. *Id.* at 1062-63. Thus, Congress simply taxed cannabis under its taxing authority, making it more expensive in order to deter its use and creating a record for state prosecution uses. And, like the Harrison Act, the Supreme Court upheld this exercise of the federal taxing authority. *United States v. Sanchez*, 340 U.S. 42, 44 (1950) ("Nor does a tax statute necessarily fall because it touches on activities which Congress might not otherwise regulate.").

These narcotics tax laws, enacted and sustained *only* under Congress' taxing power, stand in sharp contrast to the laws Congress enacted during the same period relating to pharmaceuticals in interstate commerce.

3. Under Neither The Taxing Laws Nor The Consumer Protection Laws Did Congress Attempt To Control What Medications Doctors Could Prescribe.

In none of the Acts discussed above did Congress ever attempt to regulate what substances doctors could prescribe for specific patients or conditions. In the tax acts, medical uses were exempted from coverage. And the drug purity laws were to protect consumers in the interstate market so that manufacturers could not market unsafe medicines, or medicines that were useless for the purposes the manufacturers claimed. Those laws were not a list of medicines doctors could or could not use.

Indeed, even under its commerce powers, Congress historically had *never* tried to legislate how individual doctors can medically use the substances available in interstate commerce. Historically and today, physicians can, and frequently do, prescribe and use pharmaceuticals for

"off-label" uses. Although controlled clinical trials have contributed greatly to scientific knowledge, they are not the only means of obtaining useful information about a potential treatment modality. Anecdotal cases, particularly if they are meaningful in number, may offer critically important guidance to physicians and patients. Consequently, it is well-accepted that patients may take, on prescription, an approved medication for an unapproved medical use, i.e. "off-label" prescriptions. The American Medical Association takes the position that "a physician may lawfully use an FDA approved drug product for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion." Policy 120.988, AMA Policy Compendium 1996.[8] The AMA Council on Scientific Affairs has reviewed the issue of off-label prescription use and concluded that the prevalence and clinical importance of unapproved indications are substantial, especially in the areas of oncology, rare diseases, and pediatrics. Report of the Council on Scientific Affairs 3-A-97, *Unlabeled Indications of Food and Drug Administration-Approved Drugs*. Similarly, the California Attorney General has opined that the state and federal drug approval laws were intended to protect consumers from drug manufacturers, not to interfere with the physician's judgment regarding individual patient treatment. *See* 61 Ops. Cal. Atty. Gen. 192 (1978).

And just as federal law does not prohibit doctors from trying off-label uses, it does not prohibit persons (other than

[8] This is also true of medical devices. In fact, the FDA Modernization Act (FDAMA) explicitly prohibits FDA intrusion into medical practice with regard to the off-label use of devices: "Nothing in this [Act] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396.

manufacturers) from spreading the word about off-label uses, so long as they derive no direct commercial interest from the sale or distribution of the product. Likewise, federal law does not prohibit a physician from prescribing or dispensing an unapproved drug outside the bounds of an approved investigational drug study. And federal law *explicitly* preserves the longstanding ability of both doctors and pharmacists to compound—mix up on their own—a drug product for an identified patient, without obtaining the approval the FDCA would otherwise require for a "new drug." 21 U.S.C. § 353a. All of these examples demonstrate that federal law has consistently left to doctors, and to the states that regulate them, the decisions as to which medicines should be used for particular patients.

Finally, despite the government's insistence that the law relating to medicines must be uniform to control potential problems, federal law is *not* the exclusive source of regulation of pharmaceuticals and medicines. States like California have enacted their own food and drug acts, and manufacturers may (and sometimes must) go through the California process to sell and distribute a drug in California. *See Cal. Health & Safety Code* 109875 *et seq.* (West Supp. 2004). Similarly, most states have their own laws relating to controlled substances, and many of the states classify substances differently than the federal government does. For example, Minnesota includes cannabis on Schedule II when it is used in conjunction with a doctor's research program. And although Georgia classifies cannabis as a Schedule I drug, it provides immunity from state prosecution for patients participating in Georgia's therapeutic research program. Ga. Code Ann. § 43-34-126 (2004).[9] Thus, both federal and state

[9] Indeed, 30 states currently have either classified cannabis to recognize its therapeutic potential, or they have immunized patients from prosecution if they are participating in a statutorily-authorized therapeutic research program, although a few of those programs must be approved by

law have long recognized that the issue of what medications are appropriate for particular patients is an issue for doctors and patients, within the broad outlines of state regulation of the practice of medicine.

B. The Controlled Substances Act Plowed New Ground By Making Noncommercial Intrastate Possession Of Cannabis For Medical Use A Federal Crime, Regardless Of What States Decided About Its Medical Use.

In 1970, Congress abandoned its 194-year-old position that it lacked authority to ban the wholly intrastate non-economic possession of medical substances. For the first time ever, Congress claimed the power, based solely on its interstate commerce authority, to decide for every state what substances could be used by doctors to treat patients, and what could not. Indeed, this approach "'plow[ed] thoroughly new ground and represents a sharp break with the long-standing pattern of federal . . . legislation.'" *Lopez*, 514 U.S. at 563 (citation omitted). Repealing the revenue laws such as the Harrison Tax Act and the Marijuana Tax Act, as well as fifty other laws, Congress set up what it called a "closed system" in which all substances that posed any danger were classified into five categories, whether in interstate commerce (or intrastate commerce) or not.

Deciding that cannabis had "no currently accepted medical use" Congress banned it (among other substances) outright. 21 U.S.C. § 812. For other substances it decided had medical uses, Congress placed them under more severe or less severe restraints, depending on how likely they were to be illegally diverted and used for non-medical purposes.

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the federal government, which has not yet happened. *E.g.* Ala. Code 20-2-110 *et seq.* (2004) (therapeutic research program); 720 ILCS 550/11, 550/15 (West 2004) (same); Mass. Gen. Laws ch. 94D § 1 *et seq.* (2004) (same).

When Congress enacted the CSA, most states agreed with Congress; their own state statutes reflected their own assumptions that cannabis, for example, lacked medical usefulness. Thus, for some time, Congress's encroachment into state authority caused no friction since many, if not all, state laws paralleled the federal law. However, in the 1980's, medical research began to resurface, suggesting that in fact, cannabis did have some specific therapeutic usefulness, and that for some patients, it gave relief when other medications did not. *See* 1999 Institute of Medicine Report, *Marijuana and Medicine, Assessing the Science Base* (summarizing research from 1980's and 1990's) (available at http://books.nap.edu/books/0309071550/html). In response to this emerging research, states began to reconsider their conclusions about the medical uses for cannabis, and between 1978 and 1983, thirty-five states passed some form of medical research or medical use legislation. More recently, nine states—Alaska, California, Hawaii, Maine, Nevada, Oregon, Vermont, and Washington—have established laws specifically allowing the use of medical cannabis when in consultation with a doctor.[10] Thus, based on *medical research*, many doctors have developed the view that medical cannabis appears to work better for some patients than other medicines, and, under their traditional public health authority, several states have responded to allow doctors and patients to seek the best treatment options for those patients. These states and their citizens have exercised their authority, within our federalist system, to "serve as a laboratory; and try novel social and economic

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[10] *See* Alaska Stat. §§ 11.71.090, 17.37.010 *et seq.* (Michie 2003); Cal. Health & Safety Code § 11362.5 (West Supp. 2004); Colo. Const. art. 18, § 4; Haw. Rev. Stat. Ann. § 329-121 *et seq.* (Michie Supp. 2003); Me. Rev. Stat. Ann. tit. 22, § 2383-B (West 2004); Nev. Rev. Stat. Ann. § 453A.200 (Michie Supp. 2003); Or. Rev. Stat. §§ 475.300-.346 (2003); Vt. Stat. Ann. tit. 18 § 4472 *et seq.* (2004); Wash. Rev. Code Ann. §§ 69.51.010-.080 (West 2004).

experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). And it is not just a few states who understand this principle. In response to questions about his position on states allowing the use of medical cannabis, President Bush has declared, "I believe each state can choose that decision as they so choose." *Justices Rule Against Medical Use of Marijuana*, Pittsburgh Post-Gazette, May 15, 2001, at A1.

The government and its *amici* argue at length that the entire CSA will collapse if Congress does not have the commerce power to ban instrastate possession of medical cannabis that has never been, and is not intended to be, in commerce. But this argument proves far too much. First, this decision will not lead, as *amici* claim, to some vague "underground 'medical' system." DuPont *Amici* Brief at 22. In fact, confirming that Congress lacks commerce clause power over intrastate medical, non-commercial possession and use of cannabis will allow exactly the same system of federal regulation of all medications *in interstate commerce* to continue. And for those therapeutic substances that Congress has prohibited in interstate commerce—such as medical cannabis—limiting Congress' reach to *commerce* simply ensure that *states* regulate whether those medical substances may be possessed or used outside the context of commerce.

The DuPont *Amici's* contention that the Court of Appeals' holding would allow anyone to cultivate any narcotic locally is also misplaced. Unlike Congress, states have the inherent authority (within constitutional limits) to make rational laws relating to public health, including the authority to reasonably and rationally ban or regulate dangerous products, whether in commerce or not. And the states have exercised that authority as their legislatures,

executives, and citizens see fit. Neither this Court nor the Congress can presume that states will exercise that authority badly, or not at all, as a premise for expanding Congress' delegated power. California, as well as eight other states, specifically allows the possession and use of cannabis *as medicine*, in consultation with a doctor. There is no reason to believe that these (or any other) states will suddenly decide that other dangerous substances can be homegrown in any circumstances.

C. To The Extent The CSA Regulates The Intrastate, Noncommercial Cultivation And Possession Of Cannabis For Personal Medical Purposes As Recommended By A Physician Under Valid State Law, It Is Beyond Congress' Interstate Commerce Power.

Congress' attempt to extend its reach beyond the commerce inherent in buying, selling, and manufacturing to the simple non-economic cultivation and possession, for medical purposes, of a substance that has demonstrably never been part of any commercial exchange exceeds its constitutional authority. *Amici* do not contend that Congress may not regulate medical drugs, like other products, in interstate commerce, subject to other constitutional limitations. But "the State has the sovereign right . . . to protect the . . . general welfare of the people . . . . Once we are in the domain of the reserve power of a State we must respect the wide discretion on the part of the [state] legislature in determining what is and what is not necessary." *City of El Paso v. Simmons*, 379 U.S. 497, 508-09 (1965) (quoting *East New York Savings Bank v. Hahn*, 326 U.S. 230, 232-23 (1945)) (alteration in original). Here, recognizing that intrastate cultivation, possession, and use of medical cannabis on a physician's advice under valid state law is an

activity quite distinct from the recreational use creating the interstate market about which Congress was concerned is one way to respect that state discretion, without imperiling the rest of the Controlled Substances Act. And Congress cannot bootstrap a general police power into its delegated authority simply by asserting that all instances of possession necessarily substantially impact interstate commerce.

Nor can Congress derive an undelegated power from its dissatisfaction with the way a state has exercised its reserved power. The DuPont *Amici* Brief argues that California's medical cannabis system creates "chaos" and so must be reigned in by Congress whereas another system that did not create "chaos" would presumably be allowed. DuPont *Amici* Brief at 19. But even if this assertion were true—and it is not—there is no "rescue" clause in the Constitution authorizing Congress to exceed its delegated powers when the states make "mistakes." Indeed, the power to try novel social experiments must include the power to fail. Because this experiment is confined within a state, and because it does *not* involve transactions that are economic or commercial that could truly affect interstate commerce, it is not within Congress' power to regulate.

The DuPont *Amici* Brief also argues that allowing states to determine whether patients or caregivers may grow their own non-commercial cannabis for medical purposes would lead to "widespread use" across a state. DuPont *Amici* Brief at 25. But this argument does not follow: if state law authorizes sick patients to use it with their doctor's approval, the universe of potential users is already defined. That universe will not grow (or shrink) based on a decision by this Court. Nor could the non-commercial medical cannabis distribution system—wholly within the state—hypothesized by the DuPont *Amici* in any way "disrupt" a federal system

for all other medical products that are *in interstate commerce*. The two simply do not intersect.

Finally, even good policy reasons cannot create a power in Congress that was not delegated by the Constitution. And the ones suggested here would be insufficient, even if they could. First, if there is any disincentive to the commercial research and development of medical cannabis, it is not that some states allow patients to grow their own. DuPont *Amici* Brief at 25-26. Instead, that disincentive is created by the federal ban on any use of (and much research about) cannabis. Were the federal government to lift the ban and allow medical uses, market mechanisms would certainly ensure that pharmaceutical companies would quickly solve whatever problems of purity and potency exist. And if doctors have the opportunity to prescribe a commercially available product with more predictable characteristics, it is unlikely they would prescribe home grown remedies. Second, health care professionals *have* been put in an untenable position, as the DuPont *Amici* argue, *id.* at 27, but not by the states who have enacted state laws protecting the right of patients to seek medical treatment that works for them. They have been put in that position by a Congress who concluded, for every patient in every state, that cannabis has no medical use, when many doctors and at least nine states believe otherwise Thus, as a result of federal law, doctors are forced to either withhold potentially life-saving, and certainly life-enhancing treatment, or to risk violating federal law. Limiting Congress' reach to interstate commerce, and not beyond, resolves that tension.

CONCLUSION

Because Congress' authority to regulate interstate commerce does not extend to banning intrastate, non-commercial possession of medical cannabis at a doctor's

recommendation under valid state law, this Court should conclude that the Controlled Substances Act does not preclude such possession, and should affirm the Court of Appeals' decision.

Respectfully submitted,

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IN THE

Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, *ET AL.*
Petitioners,

v.

ANGEL MCCLARY RAICH, *ET AL.*
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE CATO INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, exceeds Congress' power under the Commerce Clause as applied to intrastate possession of marijuana for medicinal use, when that use is undertaken pursuant to physician supervision in accord with California's Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5 (West Supp. 2004).

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BRIEF OF THE CATO INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF *AMICUS CURIAE*[1]

The Cato Institute was established in 1977 as a non-partisan public policy research foundation dedicated to advancing the principles of individual liberty, free markets, and limited government. Cato's Center for Constitutional Studies was established in 1989 to help restore the principles of limited constitutional government, especially the idea that the U.S. Constitution establishes a government of delegated, enumerated, and thus limited powers. Toward that end, the Institute and the Center undertake a wide range of publications and programs, including, notably, the *Cato Supreme Court Review*. Counsel of Record for Cato's brief is Professor Douglas W. Kmiec, a leading scholar of constitutional law and recently Dean of The Catholic University of America, who also previously served as Assistant Attorney General of the United States, Office of Legal Counsel, U.S. Department of Justice, during the administrations of Presidents Reagan and George H.W. Bush. The instant case raises squarely the question of the limits on the federal government's power under the doctrine of enumerated powers and is thus of central interest to the Cato Institute and its Center for Constitutional Studies.

SUMMARY OF ARGUMENT

The Court of Appeals should be affirmed. Affirmance follows from: the limited, noncommercial and intrastate medicinal use of marijuana authorized by the people of California, the responsible state judicial construction of that

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[1] In conformity with Supreme Court Rule 37, *amicus* has obtained the consent of the parties to the filing of this brief and letters of consent have been filed with the Clerk. *Amicus* also states that counsel for a party did not author this brief in whole or in part; and no person or entities other than the *amicus*, its members, and counsel made a monetary contribution to the preparation and submission of this brief.

authority, and a reasoned application of the modern Commerce Clause precedents of this Court. Because the terminology of channels, instrumentalities, and substantial effects is subject to over-extension, however, this case is also an appropriate vehicle for linking this useful, but sometimes misused, short-hand to the original understanding of the commerce power. By doing this, the Court will be giving honor to the principles of federalism so well articulated by the late Justice Powell in *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 568 (1985) (Powell, J., dissenting): "In our federal system, the States have a major role that cannot be pre-empted by the National Government. As contemporaneous writings and the debates at the ratifying conventions make clear, the States' ratification of the Constitution was predicated on this understanding of federalism."

The ratification bargain is dishonored when citizens in great physical pain are deprived of available medical treatment by a remote sovereign on the far side of the continent. Respect for state authority is abandoned when the only mildly effective therapy for a severe and inoperable illness is mocked in litigation advocacy, as it has been by the federal government here, as a "homegrown" or a "purported" medicinal treatment. Federalism is ignored when, by a thoughtful act of direct state democracy, the neighbors closest to those seeking medical relief overwhelmingly authorize the "compassionate use" of an otherwise controlled substance, but such compassion is then peremptorily denied with a recital of outworn boilerplate about how these acts of federalism "substantially affect" interstate commerce.

Modern Commerce Clause analysis falters when textual definition is separated from constitutional purpose. This is not what the founding generation intended — and this case offers an opportunity to put the original conception of the commerce power back at the core of the Court's thinking. The contours of the original understanding of the commerce power can be gleaned from consideration of three principal sources: (1) Chief Justice John Marshall's seminal opinion in

Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824); (2) the argumentation of Daniel Webster in that case, which clarifies and completes Marshall's reasoning; and, most importantly, (3) the wording of the Virginia Resolution, which is the genesis of the Commerce Clause. Together, these sources delineate the purpose underlying the commerce power, under which the federal government may act to remedy actual state regulatory incapacity and promote genuinely national interests. The purposive conception of the commerce power yields a workable framework for restraining constitutionally overbroad claims of federal legislative power — one that incorporates, refines, and supplements the best components of the modern Commerce Clause framework.

What is suggested here requires a modest elaboration of the understanding of the commerce power, but one that can do much good: By taking the opportunity to re-connect Commerce Clause analysis to this original understanding, the Court will again make it possible for citizens who depend upon the structure of the Constitution for the preservation of liberty — and, in this case, a life without unbearable pain — to "understand the principle on which this system was constructed."[2]

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[2] As Founder James Wilson more fully observed:

> I consider the people of the United States as forming one great community, and . . . the people of the different States as forming communities again on a lesser scale. From this great division of the people into distinct communities it will be found necessary that different proportions of legislative powers should be given to the governments, according to the nature, number and magnitude of their objects. . . .
>
> . . . Unless the people are considered in these two views, we shall never be able to understand the principle on which this system was constructed.

James Wilson, Pennsylvania Ratifying Convention (Dec. 4, 1787), *reprinted in* 1 *The Founders' Constitution* 62 (P. Kurland & R. Lerner eds., 1987).

ARGUMENT

Part I undertakes a brief summary of key arguments in favor of the California statute under modern precedent. As this Part demonstrates, respondents should prevail as a matter of *stare decisis* alone. Part II illustrates how re-connecting existing precedent to the underlying purpose of the commerce power helps avoid the federal over-reaching that is so evident in this case.

I. MODERN COMMERCE CLAUSE ANALYSIS SUPPORTS RESPONDENTS

A. The Compassionate Use Act Is Within The Province Of Traditional State "Expertise" Over Health Care

Justices Kennedy and O'Connor affirmed in *Lopez* that in areas of traditional state concern, where states "lay claim by right of history and expertise," the federal government ought not legislate "beyond the realm of commerce in the ordinary and usual sense of that term." *United States v. Lopez*, 514 U.S. 549, 583 (1995) (Kennedy, J., and O'Connor, J., concurring). The Compassionate Use Act, which allows for the limited use of a controlled substance under a doctor's care (Cal. Health & Safety Code 11362.5), fits squarely within an area of state expertise. Protecting the health and safety of citizens has been "primarily, and historically, . . . [a] matter of local concern." *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985). For this reason, this Court has acknowledged that the local provision of health care is a "subject of traditional state regulation." *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000). Moreover, this Court has stated that "the direct control of medical practice in the States is beyond the power of the Federal Government." *Linder v. United States*, 268 U.S. 5, 18 (1925). It is deep-seated and "elemental" that states retain "broad power" relating to the "establish[ment] and enforce[ment] of standards of conduct within its borders" that facilitates its citizens' health needs. *See Great Atlantic & Pacific Tea Co., Inc v. Cottrell*, 424

U.S. 366, 371 (1976); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954). This broad power "extend[s] naturally to the regulations of all professions concerned with health." *Id.*

Here, the State of California has exercised its historic power over local health and welfare in a deliberative and circumspect manner. In 1996, California voters, by an overwhelming 56% majority (greater than the vote percentage received by either Presidents Clinton or Bush in the state — and, for that matter, most other elected officials), approved the Compassionate Use Act as Proposition 215. The arguments for and against the proposition were clear and pointed. Doctors and nurses reported witnessing firsthand the medical benefits of marijuana, especially in respect to cancer patients. These medical professionals described how, because of side-effects of certain cancer treatments (for example, nausea induced by chemotherapy), one-third of seriously ill patients discontinue those treatments despite a 50% chance of improvement. By contrast, they argued that when standard anti-nausea drugs fail, marijuana ingested in food or by smoking is often the only medication that eases patients' nausea, permitting continued treatment.[3]

On the other side, opponents of the initiative noted that the federal government allows patients to take Marinol, an FDA-approved synthetic substitute for marijuana. The opponents also argued that the proposition might be the first step toward broader drug legalization. Finally, some members of the law enforcement community (a constituency that was divided on the topic) explained possible enforcement obstacles.[4]

In approving the Compassionate Use Act, Californians balanced these competing concerns, keeping in place tight

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[3] For a brief summary of positions in favor of Proposition 215, *see* Proposition Pamphlet, *Argument in Favor of Proposition 215, available at* http://vote96.ss.ca.gov/Vote96/html/BP/215yesarg.htm.

[4] For a brief summary of positions against the Proposition, *see* Proposition Pamphlet, *Argument Against Proposition 215, available at* http://vote96.ss.ca.gov/Vote96/html/BP/215noarg.htm.

state controls and prohibitions on marijuana outside the heavily regulated medical context. Mere possession of one ounce or less remains a crime, for example. Cal. Health & Safety Code § 11357(b). Possession with the intent to sell any amount is a felony. Cal. Health & Safety Code § 11359. Non-medicinal cultivation of any amount is a felony. Cal. Health & Safety Code § 11358. Sale, transportation, or distribution of marijuana is a felony under Cal. Health & Safety Code § 11360. There are also provisions specifically outlawing: the sales to minors, Cal. Health & Safety Code § 11361, and the sale or manufacture of marijuana paraphernalia, Cal. Health & Safety Code § 11364. Driving privileges may be suspended for marijuana violations, Cal. Veh. Code § 13202.5, and the forfeiture of vehicles is provided for upon conviction for large amounts, Cal. Health & Safety Code § 11470.

The state judicial construction of the Compassionate Use Act has been equally circumspect. First, in *People v. Mower*, 28 Cal. 4th 457 (2002), the California Supreme Court rejected claims that the Act created an immunity from arrest, either expressly or impliedly. Rather, it recognized a limited immunity from prosecution, which allows a defense at trial, and permits a motion to set aside an indictment or information prior to trial. *Id.* at 470. Thus, a defendant may raise his or her status as a qualified patient or primary caregiver as a defense at trial or in moving to set aside an indictment or information prior to trial. *Id.* at 470-74. The burden of proof as to this affirmative defense is allocated to the defendant. *Id.* at 480-81.

In similarly circumspect fashion, the court in *People v. Trippett*, 56 Cal. App. 4th 1532 (1997), *rev. denied*, 1995 Cal. LEXIS 8225 (Cal. Nov. 15, 1997), reasoned that even with a physician's recommendation or approval, a patient may not possess an unlimited quantity of marijuana under the Act. Rather, the quantity possessed, and the form and manner of its possession, must be reasonably related to the patient's current medical needs. *Id.* at 1549.

In reaching those conclusions, the state court noted that law enforcement authorities had given their support to the proposition because they did not "want to send cancer patients to jail for using marijuana" (*id.* at 1546); but at the same time, the Act carefully provided that "[n]othing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for nonmedical purposes." Cal. Health & Safety Code § 11362.5(b)(2).

B. The Compassionate Use Act Does Not Interfere With The Federal Interests Asserted Here

Against the state's claims to authority, the federal government states a national interest in controlling illicit drug trafficking and promoting safe and effective drug usage. The federal government further asserts that this Court must apply "a 'rational basis' standard that reflects broad deference to legislative judgments regarding whether the intrastate activity at issue" may be federally regulated. Brief of Petitioners at 16 (hereinafter U.S. Brief). These arguments do not withstand scrutiny.

At the outset, the government's unqualified advocacy of "broad deference" to the federal legislature fails to credit the place of federalism in our constitutional system, and this Court's commitment to it. It is reminiscent of an earlier Court's unfortunate consignment of federal-state balance to the vicissitudes of politics. *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 588 (1985) ("With the abandonment of *National League of Cities,* all that stands between the remaining essentials of State sovereignty and Congress is the latter's underdeveloped capacity for self-restraint. The problems of federalism in an integrated national economy are capable of more responsible resolution than holding that the States as States retain no status apart from that which Congress chooses to let them retain.") (O'Connor, J., dissenting). It is far more constitutionally faithful to recognize, as this Court has, that *both* the political

branches *and* the judiciary have an essential role in safeguarding the federal-state balance. "The political branches of the Government must fulfill [this role] if democratic liberty and the federalism that secures it are to endure." *Lopez*, 514 U.S. at 578 (Kennedy, J. and O'Connor, J., concurring).

Nor is the federal government's proposed "rational basis" test consistent with parallel federalism precedents. The federal-state balance is not satisfied by a rational basis inquiry when the federal government improperly commands a state to legislate or enforce federal edict, *New York v. United States*, 505 U.S. 144 (1992); *Printz v. United States*, 521 U.S. 898 (1997); or when the federal government imposes monetary liability contrary to principles of state immunity, *Kimel v. Florida Bd. of Regents*, 528 U.S. 62 (2000); *Bd. of Trustees of the Univ. of Alabama v. Garrett*, 531 U.S. 356 (2001). And it also is insufficient to answer whether the federal government has stayed within its enumerated powers.[5] In each of these contexts, the Court applies deference to Congress' legislative purpose but does not apply rational basis deference when determining whether that purpose has been accomplished through an improper invasion of state authority.

Finally, the federal interests asserted by the government as a justification for intruding on state authority are not implicated by the Compassionate Use Act. First, the California Supreme Court has held the Act does not in any way license the introduction of marijuana into the stream of commerce. *People ex rel. Lungren v. Peron*, 59 Cal. App. 4th 1383 (1997), *rev. denied*, 1998 Cal. LEXIS 1321 (Cal.

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[5] "If Congress could define its own powers [under Section 5 of the Fourteenth Amendment] by altering the Fourteenth Amendment's meaning, no longer would the Constitution be 'superior paramount law, unchangeable by ordinary means.'" *City of Boerne v. Flores*, 521 U.S. 507, 529 (1997). Congress should not be permitted to merely define its own power here, either. *See, e.g., id.* at 508 ("Congress does not enforce a constitutional [power] by changing what the [power] is.").

Feb. 25, 1998) (denying even nonprofit associations a defense under the Act, affirming that the Act only gives an affirmative defense to the patient or a patient's primary caregiver from prosecution for cultivation or possession).

Second, California's approval for the limited medicinal use of marijuana presents no interference with the FDA's new drug approval authority. That authority relates expressly to procedures pertaining to introducing a drug into the *interstate* market for sale. 21 U.S.C. §§ 355(a), (b) (2003). This Court's decision in *United States v. Rutherford*, 442 U.S. 544 (1979), sustaining the FDA's authority even as against terminally ill patients, is likewise undisturbed by the medicinal marijuana use here, which implicates no plan for interstate marketing. Acknowledging that the federalist structure of the Constitution reserves at least some components of the relationship between doctor and patient for state oversight is hardly inconsistent with *Rutherford*'s recognition that the FDA has regulatory authority over nationwide marketing of pharmaceuticals.

The acting Solicitor General writes that it is solely for Congress to "constitutionally conclude[] that the public should use only those drugs that the FDA has approved as safe and effective. . . ," U.S. Brief at 27, but FDA practice, itself, denies this unrefined claim of centralized medical direction. The Federal Food, Drug and Cosmetic Act (FDCA) does not flatly prohibit a physician from prescribing or dispensing an unapproved drug outside the bounds of an approved investigational drug study. To the contrary, it explicitly permits a physician, or a pharmacist upon a physician's order, to compound or mix a modified drug product for an identified patient, without obtaining "new drug" approval from the FDA. 21 U.S.C. § 353 (2004). In addition, patients may take, on prescription, an approved medication for an unapproved medical use — a so-called "off-label" prescription. The American Medical Association takes the position that "a physician may lawfully use an FDA approved drug product for an unlabeled indication when such use is based upon sound scientific evidence and sound

medical opinion." Policy 120.988, *AMA Policy Compendium 1996*.[6] The AMA has found this off-label authority to be particularly important in the areas of oncology and rare diseases, like those confronted by respondents. Report of the Council on Scientific Affairs 3-A-97, *Unlabeled Indications of Food and Drug Administration-Approved Drugs*.[7] The federal government's sweeping claim that it has created a highly-regulated "closed-system" with respect to controlled substances is thus contrary to federal law as it exists and as it is practiced.

Third, there is no evidence the Act will interfere with enforcement of preexisting criminal drug policy. To be sure, the federal government has argued that the Act will make it more difficult for law enforcement officials to identify possession of illicit drugs, because they will have to differentiate between cultivation and possession that is legal and that which is not. But, this argument is belied by distinctions law enforcement officers make every day. Law enforcement agents regularly are called upon to differentiate between legal and illegal conduct that manifests itself in largely the same manner. Vicodin and Oxyconton are just two examples of drugs that are available legally under a physician's care, but that are also trafficked illegally on the illicit drug market. One use is subject to prosecution, the other is not. Similarly, in states that have laws that make it legal to carry a firearm, agents must differentiate between legal and illegal gun possession.

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[6] *See also* "Off-Label Use of Marketed Drugs, Biologics and Medical Devices," *FDA IRB Information Sheet* (1998 Update), *available at* http://www.fda.gov/oc/ohrt/irbs/offlabel.html.

[7] The California Attorney General has opined that the state and federal drug approval laws were intended to protect consumers from drug manufacturers, not to interfere with the physician's judgment regarding individual patient treatment. *See* 61 Ops. Cal. Atty. Gen. 192 (1978).

In this very case, Judge Beam in dissent in the court below doubted "whether anyone can or will seriously argue that the DEA intends to prosecute these two seriously ill individuals," *Raich v. Ashcroft*, 352 F.3d 1222, 1237 (9th Cir. 2003) (Beam, J., dissenting), suggesting that a few individuals with medical needs are fully capable of being disaggregated from the main enforcement tasks of the DEA. Judge Beam cited law review commentary indicating that the DEA generally leaves minor possession cases to state officers. *Id.* at 1237 (Beam, J., dissenting). It would seem that federal law enforcement personnel on the beat have a better, more workable, grasp of the federal-state balance than their federal lawyer counterparts.

It is the federal government's failure to appreciate the federal-state balance that complicates federal law enforcement. As this Court observed in *Lopez*, "[t]he statute now before us forecloses the States from experimenting and exercising their own judgment in an area to which States lay claim by right of history and expertise, and it does so by regulating an activity beyond the realm of commerce in the ordinary and usual sense of that term." *Lopez*, 514 U.S. at 583 (Kennedy, J., and O'Connor, J., concurring). Indeed, various local counties and police departments in California have already devised means by which to certify patients who are eligible to use marijuana for medical purposes.[8]

C. The Object Of The California Regulation Does Not Qualify As "Commerce"

Congress' power to regulate "commerce" under modern Commerce Clause jurisprudence does not extend to objects

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[8] In this regard, a certification card in Arcata, California, "contains an identification number that officers in the field can verify by contacting the dispatcher." Laura M. Rojas, Comment, *California's Compassionate Use Act and the Federal Government's Medical Marijuana Policy: Can California Physicians Recommend Marijuana to Their Patients Without Subjecting Themselves to Sanctions*?, 30 McGeorge L. Rev. 1373, 1421 (1999) (noting a similar effort in Marin County).

(*i.e.*, actors, products, or conduct) that fail to exhibit a demonstrated "commercial nexus." *See, e.g., Lopez*, 514 U.S. at 557, 558 (Congress may not use "a relatively trivial impact on commerce as an excuse for broad general regulation of state activities"; rather, "a general regulatory statute" must bear a "substantial relation to commerce") (internal quotations omitted); *id.* at 580 (Kennedy, J., concurring) ("neither the actors nor the commercial character, and neither the purpose nor the design of the statute have an evident commercial nexus"). The activity at issue here — intrastate activity occurring outside the stream of commerce — lacks any such nexus and is therefore beyond the scope of federal legislative power. *See, e.g., United States v. Morrison*, 529 U.S. 598, 611 (2000) ("in those cases where we have sustained federal regulation of intrastate activity based upon the activity's substantial effects on interstate commerce, the activity in question has been some sort of economic endeavor").

To be sure, marijuana is a federally-controlled substance.[9] Congress enacted the Controlled Substances Act (CSA) "to deal . . . with the growing menace of drug abuse in the United States." H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 1 (1970). But, as discussed in Parts I.A and I.B

[9] For a summary of the CSA's relevant provisions, *see Raich*, 352 F.3d at 1224:

> The CSA establishes five "schedules" of certain . . . "controlled substances." 21 U.S.C. §§ 802(6), 812(a). Marijuana is a schedule I controlled substance[,] *id.* § 812(c)[,] [based on a finding] (1) that the substance "has a high potential for abuse"; (2) that the substance "has no currently accepted medical use in treatment in the United States"; and (3) that there is "a lack of accepted safety for use of the drug or other substance under medical supervision." *Id.* at § 812(b)(1). . . . Among other things, the CSA makes it unlawful to knowingly or intentionally "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance," except as provided for in the statute. 21 U.S.C. § 841(a)(1). Possession . . . is also unlawful. *Id.* § 844(a).

above, the California statutory framework *prohibits* interstate sale, manufacture, or distribution of any drug — and authorizes only the medicinal, intrastate use of marijuana under medical supervision. Furthermore, although Congress, in enacting the CSA, made findings on both interstate and intrastate *manufacturing* and *distribution* of controlled substances and their affects on interstate commerce, Congress made no finding concerning the intrastate, noncommercial cultivation and possession of marijuana for personal *medical* purposes as recommended by a patient's physician. *See* 21 U.S.C. §§ 801(3)-(6). As the court below pointed out, the "limited use [of cannabis in this case] is clearly distinct from the broader illicit drug market — as well as any broader commercial market for medicinal marijuana — insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." *Raich*, 352 F.3d at 1228.

The federal government here seeks to obscure the intrastate, noncommercial character of the activity at issue by adducing this Court's broadest expositions of the commerce power[10] in *Wickard v. Filburn*, 317 U.S. 111 (1942), and *United States v. Darby*, 312 U.S. 100 (1941); the government, however, pays short shrift to this Court's subsequent *rejection* of the argument that intrastate non-commercial activities are a basis for aggregation under the "substantial effects" test. *Morrison*, 529 U.S. at 617 ("We accordingly reject the argument that Congress may regulate noneconomic . . . conduct based solely on that conduct's aggregate effect on interstate commerce.").[11]

[10] The *Lopez* Court characterized *Wickard* as "perhaps the most far reaching example of Commerce Clause authority over intrastate activity." *Lopez*, 514 U.S. at 560. The *Darby* Court's unfortunate trivialization of the Tenth Amendment as little more than a "truism" was unnecessary, unfaithful to the Constitution's structure, and surely was superseded by the decisions of the modern Court. *See New York v. United States*, 505 U.S. 144 (1992); *Printz v. United States*, 521 U.S. 898 (1997).

[11] While the record in this as-applied challenge demonstrates a complete absence of interstate or intrastate commercial activity, the

Moreover, even assuming *Wickard* and *Darby* apply here, both cases in fact *undermine* the government's case: Both undeniably involved instances of *economic* policy in a way that the activity here, in *Lopez*, and in *Morrison* do not. As the *Wickard* Court observed, the purpose of the regulation in that case "was to increase the market price of wheat, and to that end to limit the volume thereof that could affect the market. It can hardly be denied that a factor of such volume and variability as home-consumed wheat would have a substantial influence on price and market conditions." *Wickard*, 317 U.S. at 128. The home consumption in *Wickard* was thus all about, as the government acknowledges, "Congress's broader regulation of the supply, demand, and prices in the interstate wheat market. . . ." U.S. Brief at 15. The overriding economic considerations behind *Darby* are also likewise apparent. The Court accepted Congress' thinking that goods made in a substandard labor environment could be kept out of the national market. The Court reasoned that the labor conditions needed to be addressed nationally because wages and hours could not be effectively addressed by any single state since the market would naturally produce a price advantage for employers utilizing a lower wage scale.

In short, a faithful application of modern precedent leads to the conclusion that there is no federal "commercial" interest at stake here. Medicinal consumption of home-grown marijuana, administered under a doctor's oversight, pursuant to a validly-enacted statute, is a wholly intrastate activity that: (1) exists outside the stream of (legal or illegal) "commerce" within the meaning even of *Wickard* or *Darby*, and (2) under *Lopez* and *Morrison* cannot be aggregated. Unlike in *Wickard*, the facts at bar demonstrate no attempt to

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federal government asserts, without any factual basis, that personal medical use of a drug is "economic activity." U.S. Brief at 21. This is unexplained and is far less even than "inference [piled] upon inference." *Lopez*, 514 U.S. at 567.

consume goods that state law would permit to be made available to an interstate market. By comparison, farmer Filburn faced no relevant state law limitation upon the disposition of his wheat crop and was thus legally empowered to frustrate federal objectives. And, unlike in *Darby*, there is no state legal authority to introduce into the *inter*state market goods that the federal government desires to exclude.[12]

II. THE COURT SHOULD TAKE THIS OPPORTUNITY TO ANCHOR MODERN COMMERCE CLAUSE ANALYSIS TO THE ORIGINAL UNDERSTANDING OF THE COMMERCE POWER

A. Definitional Formulations Of The Commerce Power, Unattached To The Underlying Constitutional Purpose Of The Power, Risk Slighting State Authority

The analysis in Part I illustrates that the modern Commerce Clause framework favors the respondent and is capable of rendering a result consistent with the intended federal-state balance. However, definitions unattached to the original understanding or purpose of the commerce power are more easily subject to manipulation and error. Thus, the government's primary argument consists of little more than a series of scholastic definitional *assertions* — that personal

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[12] Again, in wholesale denial of the decision in *Morrison*, the federal government claims that *Wickard* allows Congress to regulate intrastate activity "which itself may not be overtly commercial in nature." U.S. Brief at 15. Here, the federal government confuses the well-established principle that Congress' motivation for regulation is irrelevant with the proposition, rejected in *Lopez* and *Morrison*, that non-commercial acts cannot be aggregated for purposes of substantial effects analysis. The first principle properly keeps the Court out of legislative policymaking. The latter *Morrison* proposition, however, ensures that the Court can meaningfully demarcate federal-state lines of authority. The two inquiries must not be conflated.

medical use of a drug is "economic activity" (U.S. Brief at 21) that is not "overtly commercial," but is nonetheless in aggregate "commercial" enough (U.S. Brief at 15, 21) or "substantial" enough (U.S. Brief at 20) to be counted as "substantially related to" interstate commerce and within the scope of federal authority.

The singular reliance on such conclusory assertions of federal power ought not to be permitted to overwhelm the deeper structural considerations of original understanding that have guided the Court so well elsewhere. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952) (constraining executive power); *INS v. Chadha*, 462 U.S. 919 (1983) (constraining legislative power). Members of this Court have noted this analytical omission, observing that, of the many structural elements of the Constitution (the separation of powers, checks and balances, and federalism), only with respect to federalism has there been "much uncertainty respecting the existence, and the content, of standards that allow the Judiciary to play a significant role in maintaining the design contemplated by the Framers." *Lopez*, 514 U.S. at 575 (Kennedy, J., and O'Connor, J., concurring).

The Constitution's text is unassailably the locus of interpretative effort, and other short-hand rubrics ("channels," "instrumentalities," "substantial effects") must be understood in a way that is faithful to that text. Justice Thomas has tellingly noted the textual difficulty surrounding the "substantial effects" prong, for example, writing that "[t]he Commerce Clause does not state that Congress may 'regulate matters that substantially affect commerce . . .'"; indeed, "the Framers could have drafted a Constitution that contained a 'substantially affects interstate commerce' clause had that been their objective." *Lopez*, 514 U.S. at 587-88 (Thomas, J., concurring). They did not. Instead, the Framers drafted a Constitution that gave Congress the power "to regulate Commerce . . . among the several States, . . ." U.S. Const. art. I, § 8. The textual meaning of this grant of power is crystallized only when the Clause is interpreted in harmony

with the *purpose* that the Framers intended this grant to accomplish.

That purpose is revealed by examining John Marshall's seminal opinion in *Gibbons v. Ogden*, *supra*; Daniel Webster's oral argument in that case; and the Virginia Resolution, which was the genesis of the Commerce Clause. Together, these sources, examined below, underscore that the Framers granted the commerce power to Congress with an overarching aim: to empower the national goverment to vindicate genuinely national interests — that is, those held by the nation as a whole, such as interstate movement and transportation, communication, or national defense — or to address a commercial subject that cannot be addressed by an individual state without undermining the policies of other states.

Recurring to the Founders' purpose is not an invitation to resurrect the Court's one-time practice of declaring some purposes unacceptable by its own lights. California and the respondents should not prevail in this litigation because a transient majority of the Court thinks the manner in which California has chosen to address the health of its citizens is important or wise. No, California and the respondents should prevail because interpreting the CSA to preclude the Compassionate Use Act does not serve the underlying purpose of the commerce power, and, therefore, no federal enactment can be construed to displace the states and still be faithful to the original understanding.

B. John Marshall Opens The Door To A Purpose-Based And Principled Commerce Clause Analysis In *Gibbons v. Ogden*

The correct analytical approach is made plain by a consideration of Chief Justice John Marshall's decision in *Gibbons v. Ogden*, *supra*. The significance of Marshall's *Gibbons* instruction for discerning the scope of reserved state authority is often overlooked since in that context the purposive inquiry vindicated federal authority. In truth,

however, the guiding originalist principle is the same in either case.

The issue in *Gibbons* was whether a federal law licensing ships to engage in the "coasting trade," under which Gibbons operated, preempted a New York law granting a thirty-year monopoly, held by Ogden, to ply the waters between New York and New Jersey. *See, e.g., Ogden v. Gibbons*, 17 Johns. 488 (N.Y. 1820), *rev'd*, 22 U.S. (9 Wheat.) 1 (1824). The effect of New York's monopoly grant, of course, was to preclude Gibbons from operating under his federal license. In seeking to give the Commerce Clause its full and accurate meaning, Chief Justice Marshall pays attention to the words of the text, but begins his argument with a discussion about how to interpret constitutional text. Thus, he is concerned to avoid not only a "narrow construction, which would cripple the [new federal] government, and render it unequal to the object for which it is declared to be instituted . . . ," but also, and most importantly for the present case, how an "enlarged construction" would slight the reserved sovereign authority of the several states. *Gibbons*, 22 U.S. at 188. Marshall's focus is thus squarely fixed upon the very purpose of the government the Constitution creates. He writes: "If . . . there should be serious doubts respecting the extent of any given power, it is a well settled rule, that the objects for which it was given . . . should have great influence in the construction." *Id.* at 188-89. Finally, to the same effect: "We know of no rule for construing the extent of such powers [as the commerce power], other than is given by the language of the instrument which confers them, taken in connexion [sic] *with the purposes* for which they were conferred." *Id.* at 189 (emphasis added).

Clearly, Marshall thinks it important not simply to engage in definitional analysis but to inquire about the "purposes" for which the Constitution's powers, and the Constitution itself, were instituted. Only in this manner, he suggests, will we be able to reach a true "construction" — that is, one that gives due regard to *both* enumerated federal

power *and* reserved state authority. Unfortunately, however, as scholars have pointed out, Marshall short-cuts analysis at this point. *See* Roger Pilon, *Freedom, Responsibility, and the Constitution: On Recovering Our Founding Principles*, 68 Notre Dame L. Rev. 507, 533-37 (1993). Rather than elaborating the complete inquiry, he jumps rather quickly to the conclusion that "commerce" includes navigation, not mere "traffic" or the interchange of commodities. He is correct, of course, but the closest he comes to overtly identifying the functional account of the Commerce Clause is to say that "[t]he power over commerce, including navigation, was one of the primary objects for which the people of America adopted their government . . ." *Gibbons*, 22 U.S. at 190. That is true, and important, but it doesn't fully disclose the functional account; for Marshall's use of "objects" here anticipates, but only suggests — without full elaboration — why federal regulation of navigation coincides with the constitutional purpose of the commerce power. Nevertheless, as discussed below, it is obvious that to reach his result, Marshall employed both the text and the purpose underlying the text to fairly consider both the federal *and* state sides of the commerce power.

C. The Federal And State Sides Of The Commerce Power Are Best Understood In Relation To The Original Purpose Of The Underlying Virginia Resolution

To grasp the full import of the commerce power on *both* its federal *and* state side one must necessarily ask: why should the regulation in question come from the federal government? As a matter of original understanding, this can only be made evident by making reference to the Sixth Virginia Resolution of 1787 (Virginia Resolution), from which the commerce power was derived. *See* Douglas W. Kmiec, *Rediscovering a Principled Commerce Power*, 28 Pepp. L. Rev. 547, 560-62 (2001). The Virginia Resolution provides:

> [T]hat the National Legislature ought to possess the Legislative Rights vested in Congress by the

> Confederation; and moreover, to legislate in all cases for the general interests of the union, and also in those cases to which the States are separately incompetent, or in which the harmony of the United States may be interrupted by the exercise of individual Legislation.

Records of the Debates in the Federal Convention of 1787 as Reported by James Madison 389 (Charles C. Tansill ed., Legal Classics Library 1989) (1927) (hereinafter Madison's Journal); also found in *Notes of Debates in the Federal Convention of 1787 Reported by James Madison* 380 (W.W. Norton & Co. 1966). Constitutional Convention delegate Gunning Bedford Jr. added the language to legislate for the "general interests of the union," which he explained simply meant to emphasize that states were separately incompetent to legislate on such subjects. Edmund Randolph, Governor of Virginia and chief sponsor of the original "separate incompetence" language, was troubled by Bedford's proposal:

> Mr. RANDOLPH. This is a formidable idea, indeed. It involves the power of violating all the laws and Constitutions of the States, and of intermeddling with their police. The last member of the sentence [regarding interrupted harmony] is also superfluous, being included in the first [regarding general interests].
>
> Mr. BEDFORD. It is not more extensive or formidable than the clause as it stands: no State being separately competent to legislate for the general interest of the Union.

Madison's Journal, *supra*, at 389-90.

Bedford's language carried, over Randolph's objections, and it was this modified vision of legislative power that the Committee of the Whole referred to the Committee of Detail, on July 26, 1787. 1 Jonathan Elliot, *Debates in the Several State Conventions on the Adoption of the Federal Constitution* 221 (2d ed. 1836). Randolph was on that

Committee, which promptly converted the more broadly worded Virginia Resolution into the specific list of enumerated powers found in Article I, Section 8. Bedford did not object to the replacement of his wording with a specific list of enumerated powers, presumably because the list accomplished all that Bedford had intended. Neither Bedford nor any other Founder intended the Commerce Clause to become a "sweeping clause" that could redraw the federal-state balance upon congressional enactment. As Robert L. Stern has commented:

> Significantly, the Convention did not at any time challenge the radical change made by the committee [of detail] . . . . It accepted *without discussion* the enumeration of powers made by the committee which had been directed to prepare a constitution based upon the general propositions that the Federal Government was "to legislate in all cases for the general interests of the Union . . . and in those to which the states are separately incompetent." . . . This absence of objection to or comment upon the change is susceptible of only one explanation — that the Convention believed that the enumeration conformed to the standard previously approved, and that the powers enumerated comprehended those matters as to which the states were separately incompetent and in which national legislation was essential.

Robert L. Stern, *That Commerce Which Concerns More States Than One*, 47 Harv. L. Rev. 1335, 1340 (1934).

Even this brief reference to the Virginia Resolution reveals how Marshall was able to so quickly ascertain the scope of federal power in *Gibbons* and how that outcome coincided with Madison's own proposition that the national government was to have "compleat authority in all cases which require uniformity." 2 *The Writings of James Madison* 345 (G. Hunt ed., 1904). Focusing on the Resolution is helpful because it moves the Court beyond the tangled

debates over "commerce," which tend to wax and wane, depending on one's ideology, between plenary power and that strictly necessary to manage the concerns of the eighteenth century. *See generally* Arthur B. Mark, III, *Currents in Commerce Clause Scholarship Since* Lopez: *A Survey*, 32 Cap. U. L. Rev. 671 (2004); *see also* Grant S. Nelson & Robert J. Pushaw, Jr., *Rethinking the Commerce Clause: Applying First Principles to Uphold Federal Commercial Regulations but Preserve State Control Over Social Issues*, 85 Iowa L. Rev. 1 (1999) *and* Randy E. Barnett, *The Original Meaning of the Commerce Clause*, 68 U. Chi. L. Rev. 101 (2001). Under the Virginia Resolution, "among the several states" was a synonym for power directed at either vindicating a national commercial interest — that is, one held by the nation as a whole, like interstate movement and transportation, communication, or national defense — or a commercial subject that cannot be addressed by an individual state without undermining the policies of other states.

It may be objected that dividing what is federal from what is local in reliance upon principles of national interest or state incapacity is too vague and manipulable to sustain such division. In the analytical terms of former Stanford Dean Kathleen Sullivan, the effort is too much standard and not enough rule. Kathleen M. Sullivan, *The Justices of Rules and Standards*, 106 Harv. L. Rev. 22, 58-60 (1992) (noting that rules limit discretion; standards confer it and specifically "tend[] to collapse decisionmaking back into the direct application of the background principle or policy . . . "). There is truth to this objection, but it is a truth that must be confessed about virtually *any* interpretative exercise. The real question is whether reference to the Virginia Resolution assists this Court in the preservation of constitutional structure. The answer is clearly, yes. In this respect, the specific clauses of the Resolution guide judicial inquiry into purpose, asking: (1) whether the states are severally incompetent; (2) whether the harmony of the United States may be interrupted by individual state legislation; and (3)

whether the interest being legislated affects the "general interests of the Union."

D. Daniel Webster's Argument In *Gibbons* Completes And Explains John Marshall's Analysis — Revealing What Is National And What Is Local

The prevailing counsel in *Gibbons* was Daniel Webster, who explained vividly how the "general interests of the Union" in navigation were being undermined in the waters surrounding New York City in 1824. Argued Webster:

> By the law of New-York, no one can navigate the bay of New-York, the North River, the Sound, the lakes, or any of the waters of that State, by steam vessels, without a license from the grantees of New-York, under penalty of forfeiture of the vessel.
>
> By the law of the neighbouring State of Connecticut, no one can enter her waters with a steam vessel having such license.
>
> By the law of New-Jersey, if any citizen of that State shall be restrained, under the New-York law, from using steam boats between the ancient shores of New-Jersey and New-York, he shall be entitled to an action for damages, in New-Jersey, with treble costs against the party who thus restrains or impedes him under the law of New-York! This act of New-Jersey is called an act of retortion against the illegal and oppressive legislation of New-York; and seems to be defended on those grounds of public law which justify reprisals between independent States.
>
> It would hardly be contended, that all these acts were consistent with the laws and constitution of the United States. If there were no power in the *general* government, to control this extreme belligerent legislation of the States, the powers of

> the government were essentially deficient, in a most important and interesting particular. . . .

22 U.S. at 4-5 (Daniel Webster, for the Plaintiff) (emphasis added).

It is instructive that Webster spent little time trying to do what the federal government belabors in its briefing in this case; namely, merely asserting that something is "commerce," or an activity that substantially affects it. Webster termed it vain to look for a precise or exact definition. That, he said, was not the way the Constitution proceeded. Instead, the extent of the power was to be measured by its object. And what was the object or prevailing purpose of the commerce power? To rescue (Webster's word) the general Union from "the embarrassing and destructive consequences, resulting from the legislation of so many different States, and to place it under the protection of a uniform law." *Id.* at 11 (Daniel Webster, for the Plaintiff).

Webster did not envision a commerce power without limit. Indeed, the commerce power was not to consume the state's separate sovereignty; rather, the Court was to interpret the power to keep the interests of the two governments "as distinct as possible. The general government should not seek to operate where the states can operate with more advantage to the community; nor should the states encroach on ground, which the public good, as well as the constitution, refers to the exclusive control of Congress." *Id.* at 17 (Daniel Webster, for the Plaintiff).

With reference to the Virginia Resolution and Webster's argumentation based upon it, the enigmatic nature of Chief Justice Marshall's opinion in *Gibbons* is completed and given clarity. Now it is obvious why Marshall could so easily construe commerce to include navigation, which on its face to every first year law student seems a non sequitur to commerce. The obscurity drops away when navigation is linked not to commercial activity *per se*, but to an interest that must be held by the union of the states in order to avoid

imperiling national interests. Indeed, Marshall's decisional words directly connect the concerns of the Virginia Resolution to the scope of the commerce power, and in so doing state a faithful constitutional understanding of both the federal and state sides of the commerce power. He wrote:

> The genius and character of the whole government seem to be, that its action is to be applied to all the external concerns of the nation, and to those internal concerns which affect the States *generally*; but not to those which are completely within a particular State, which do not affect other States, and with which it is not necessary to interfere, for the purpose of executing some of the general powers of the government. The completely internal commerce of a State, then, may be considered as reserved for the State itself.

Gibbons, 22 U.S. at 195 (emphasis added).

E. The Federal Government's Argument Disregards The Purpose Of The Commerce Power And Defies Original Understanding

John Marshall put into Supreme Court opinion what Gunning Bedford, Jr. meant when he said, "[N]o state [is] separately competent to legislate for the general interest of the Union." Madison's Journal, *supra*, at 362. Without this grounding in original understanding, we forget this principled limitation. A "national interest" is not synonymous with simply a "very important" political topic, as the argumentation of the acting Solicitor General's brief would have this Court believe. His reliance on the cumulative or substantial effects element alone obscures, rather than illuminates, the principle of the Virginia Resolution. In so doing, he is unfaithful to the original understanding and, in this instance, the power reserved to the states. In a different case, disregarding the purposive base of the Virginia Resolution might understate federal interests. To ask whether an individual action "substantially affects" interstate

commerce, without reference to the purpose of the granted power, is to ask an incomplete question.

A principled inquiry, by contrast, seeks to identify the presence or absence of a commercial interest that can only be claimed by the nation as a whole or that must be addressed nationally because of demonstrated state incapacity. And demonstrated state incapacity must be theoretically as well as *practically* grounded, not merely rhetorically asserted. In this respect, incapacity should mean that an individual state's regulatory activity would actually be defeated by the competing regulatory policies of other states.

A standard informed by the Virginia Resolution facilitates sorting that which is national from that which is local and better grounds the Court's modern commerce decisions. In *Morrison*, for example, the federal government insisted that "substantial effect" could be found in relation to the voluminous congressional record on gender-based violence. But there, fidelity to original understanding was not measured by the page, but with an assessment of whether the "general interests of the Union" necessitated a federal cause of action for intrastate rape. Despite the mountainous congressional testimony, there was no principled reason why individual states could not adopt rape shield laws or harsher civil or criminal penalties for violent assaults on the basis of gender animus. Citizens migrate where personal safety is better secured, not the converse. So, too, one would expect citizens to be attracted to states exhibiting a reasoned interest in their personal health and respect for individual medical judgment. As a general matter, citizens migrate toward greater freedom, and acknowledging the state side of the commerce power will often sharpen state competition for economic freedom, which can be easily deadened by unwarranted federal intrusion.[13]

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[13] Since commerce is mostly a private sector matter, with government enforcing the rules, there is no reason to suppose that the federal government should do so. Under our common law system, most of the rules of commerce began as informal customs or conventions. They evolved over centuries and have simply been "recognized," and sometimes modified, by courts and legislatures as the need arose. *See* F. Hayek, 1 *Law, Legislation, and Liberty* 72-93 (1973). Under our system of limited government, therefore, there is a strong presumption that people can regulate their own affairs, and that government is necessary only when that presumption fails, leading to a case or controversy that is brought before a court. The Tenth Amendment provides that the "powers not delegated to the United States . . . are reserved to the States respectively, *or to the people*." U.S. Const. amend. X (emphasis added).

The same reasoning makes this case straightforward. There is no evidence that California's regulatory policy in any way defeats parallel regulatory activity in another jurisdiction — state or federal. To the contrary, as discussed at length in Section I.A, the California statute prohibits and criminalizes any activity that would implicate interstate trade of banned substances. As a matter of original understanding, states are more, not less, competent to regulate the health interests of their individual citizens. Instead of posing intractable questions about what does and does not substantially affect interstate commerce, the purposive, originalist inquiry asks a practical question: Does the state's regulatory scheme demonstrably act to defeat the regulatory regimes of other states or an interest held by the nation as a whole?

Some problems, of course, are national. Yet, in that case too, anchoring commerce power analysis upon the Virginia Resolution clarifies, for it suggests that trans-boundary air and water resources, for example, may be protected on a national level. The federal government has that power so long as the Congress sufficiently identifies that its legislative interest is a type of migratory resource that is inherently plagued by conflicting regulatory schemes. *Cf. Solid Waste Agency v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173-74 (2001) (finding the federal interest not precisely identified, but suggesting it could be). Air and water resources rarely inhabit one state. It is the common nature of the resource that makes many questions involving

these resources collapse into a costly and wealth-minimizing regulatory war between conflicting state jurisdictions, absent a national solution. Similarly, Congress' power to remedy discrimination on the basis of race is not obviated by the Virginia Resolution. Federal laws banning discrimination at public accommodations, such as motels and restaurants, vindicate a constitutional interest (racial nondiscrimination) legally held by the nation as a whole. That national interest need not rest upon awkward inquiries into the quantities of goods and services held in trade. *Cf. Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241 (1964); *Katzenbach v. McClung*, 379 U.S. 294 (1964). In the case at bar, by contrast, there is — to paraphrase Daniel Webster — no *demonstrated* state incapacity, no *demonstrated* federal-state conflict, and no *general* interest of the union at stake. California should remain free to experiment within the bounds of its regulatory competence.

It should not be surprising that a return to constitutional purpose does not deny the "practical realities" of the twenty-first century, even as it supplies a healthy reminder of the states' primary role in the definition of crime. In *Federalist* No. 17, Hamilton writes: "There is one transcendant [sic] advantage belonging to the province of the State governments . . . I mean the ordinary administration of criminal and civil justice. This, of all others, is the most powerful, most universal, and most attractive source of popular obedience and attachment." *The Federalist* No. 17, at 120 (Alexander Hamilton) (Clinton Rossiter ed., 1961). Moreover, returning to a principled definition of the commerce power echoes the Court's own assessment that "[t]he States possess primary authority for defining and enforcing the criminal law." *Brecht v. Abrahamson*, 507 U.S. 619, 635 (1993) (quoting *Engle v. Isaac*, 456 U.S. 107, 128 (1982)). This is profoundly related to political accountability. The "formation, execution, or review of broad public policy . . . go to the heart of representative government." *Sugarman v. Dougall*, 413 U.S. 634, 647 (1973) (cited in *Gregory v. Ashcroft*, 501 U.S. 452, 462 (1991)). The direct and primary

political accountability reserved for the states would become illusory, however, "[w]ere the Federal Government to take over the regulation of entire areas of traditional state concern, areas having nothing to do with the regulation of commercial activities." *Lopez*, 514 U.S. at 577 (Kennedy, J., and O'Connor, J., concurring).

CONCLUSION

The federal government cannot sustain the application of the CSA to the noncommercial, intrastate use of medicinal marijuana under the California Compassionate Use Act. This becomes apparent the moment the Court reflects fully upon the Virginia Resolution and why the people of America gave the federal government power over interstate commerce (which was indeed one of their primary reasons for adopting a new constitution).

The same answer also can be partly gleaned from the "dormant" or "negative" Commerce Clause cases that vindicate federal interests against state protectionist barriers to the free flow of commerce. Richard A. Epstein, *The Proper Scope of the Commerce Power*, 73 Va. L. Rev. 1387, 1389 (1987). In *Federalist* No. 11, Hamilton remarked that the states had "fettered, interrupted and narrowed" commerce. *The Federalist* No. 11, at 90 (Alexander Hamilton) (Clinton Rossiter ed., 1961). Under the new plan, he continued, "[a]n unrestrained intercourse between the states themselves will advance the trade of each, . . . [and] [t]he veins of commerce in every part will be replenished from a free circulation of the commodities of every part." *Id.* at 89. Justice Johnson made the same observation in his concurrence in *Gibbons*: "If there was any one object riding over every other in the adoption of the constitution, it was to keep the commercial intercourse among the States free from all invidious and partial restraints." *Gibbons*, 22 U.S. at 231 (Johnson, J., concurring).

But the dormant Commerce Clause captures only the federal side of the commerce power. The Virginia Resolution in full supplies the missing analytical means to

vindicate state interests when the "general interests of the union" are not implicated or the "states are not separately incompetent" to act. When both federal and state interests are harmoniously honored, the original understanding is once again revealed. And by this revelation, the modern Court keeps faith with the arguments for the Constitution's ratification, which cannot be too often remembered.

Even before the Tenth Amendment was added to the Constitution, its point was articulated by Hamilton in *Federalist* No. 32: "the rule that all authorities, of which the States are not explicitly divested in favor of the Union, remain with them in full vigor . . . is clearly admitted by the whole tenor . . . of the proposed Constitution." *The Federalist* No. 32, at 201 (Alexander Hamilton) (Clinton Rossiter ed., 1961).

California remains "in full vigor" of the power to address the individual health needs of her citizens.

Respectfully submitted.

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In The

Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, *et al.*,

Petitioners,

v.

ANGEL McCLARY RAICH, *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF COMMUNITY RIGHTS COUNSEL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate cultivation and possession of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use.

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INTEREST OF THE *AMICUS CURIAE*[1]

Community Rights Counsel (CRC) is a nonprofit, public interest law firm that assists government officials in defending against constitutional challenges to federal, State, and local protections, with a particular emphasis on challenges under the Takings Clause, Commerce Clause, and Supremacy Clause.

Since its founding in 1997, CRC has filed *amicus* briefs with this Court in support of many federal, State, and local government laws, including regional protections for Lake Tahoe, *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302 (2002), State programs to fund legal services for the poor, *Brown v. Legal Found. of Wash.*, 538 U.S. 216 (2003), State remedies against negligent health maintenance organizations, *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488 (2004), regional initiatives to promote clean air, *Engine Mfrs. Ass'n v. South Coast Air Quality Mgmt. Dist.*, 124 S. Ct. 1756 (2004), State wetland protections, *Palazzolo v. Rhode Island*, 533 U.S. 606 (2001), State common law remedies against negligent pesticide manufacturers, *Eyl v. Ciba-Geigy Corp.*, 123 S. Ct. 2642 (2003), and municipal requirements for addressing toxic waste contamination, *City of Lodi v. Fireman's Fund Ins. Co.*, 538 U.S. 961 (2003). CRC also has represented scores of governmental *amici* in federal and State appellate courts across the country.

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[1] Counsel for the parties did not author this brief in whole or in part. No person or entity other than the *amicus* made a monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of this brief, and letters of consent have been filed with the Clerk.

Although we oppose preemption of State law under the Supremacy Clause absent a clear statement of intent to preempt, Congress clearly has invoked its Commerce Clause authority to prohibit the cultivation and distribution of marijuana for medical use. CRC has a strong interest in ensuring stability in Commerce Clause jurisprudence and legislative flexibility to address national concerns embraced by Congress's enumerated powers.

ARGUMENT

We begin with a disclaimer. While we have sympathy for those who turn to marijuana for relief from serious illness and suffering, we take no position on the policy questions posed by medical marijuana use. The question raised by this case is: Who decides? The acceptability of cultivation and distribution of marijuana for medical use should be settled through the political process by those accountable to the voters, not by the federal courts through the unduly narrow reading of the Commerce Clause adopted by the Ninth Circuit.

As recent Commerce Clause cases make clear, the Court polices the "outer limits" of Congress's authority, *United States v. Lopez*, 514 U.S. 549, 566 (1995), but at the same time it places a high value on continued stability in this area of the law. In both *Lopez* and *United States v. Morrison*, 529 U.S. 598 (2000), the Court was careful to preserve longstanding Commerce Clause precedent so as not to disrupt the legitimate expectations of citizens who have come to rely on basic federal protections. *Lopez*, 514 U.S. at 555-68 (analyzing and applying post-1937 Commerce Clause precedent); *Morrison*, 529 U.S. at 607-19 (same).

As stressed by Justices Kennedy and O'Connor, courts should continue to exercise "great restraint" in reviewing Commerce Clause enactments. *Lopez*, 514 U.S. at 568 (Kennedy, J., with O'Connor, J. concurring). This judicial restraint reflects the simple reality that "the Court as an institution and the legal system as a whole have an immense stake in the stability of our Commerce Clause jurisprudence as it has evolved to this point." *Id.* at 574.

We show below that well-established precedents provide two straightforward rules of law that compel reversal: 1) Congress may regulate economic activity such as intrastate marijuana cultivation or distribution that, when aggregated with similar economic activity, has a substantial effect on interstate commerce; and 2) where Congress regulates a unified class of activity that substantially affects interstate commerce such as drug traffic, a court should not excise out individual applications of the federal program to intrastate activity, especially where the regulation of intrastate activity is necessary to control interstate activity effectively.

I. CONGRESS MAY REGULATE THE INTRASTATE CULTIVATION OR DISTRIBUTION OF MARIJUANA BECAUSE IT SUBSTANTIALLY AFFECTS INTERSTATE COMMERCE.

This case is controlled by *Wickard v. Filburn*, 317 U.S. 111 (1942). In *Wickard*, the central issue was whether the federal government could "extend[] federal regulation to [wheat] production not intended in any part for commerce but wholly for consumption on [Filburn's] farm." *Id.* at 118. It was immaterial to the Court that Filburn's activity involved only wheat cultivation and consumption, as opposed to sale or trade. *Id.* at 120 ("[Q]uestions of the

power of Congress are not to be decided by reference to any formula which would give controlling force to nomenclature such as 'production' and 'indirect' and foreclose consideration of the actual effects of the activity in question upon interstate commerce."); *id.* at 125 (although Filburn's wheat cultivation "may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce.").

Likewise, it made no difference to the *Wickard* Court that Filburn's cultivation and consumption by itself had only a miniscule effect on interstate commerce. Congress could regulate that cultivation because it could rationally conclude that, when aggregated with all similar economic activity, it had a substantial effect: "That appellee's own contribution to the demand for wheat may be trivial by itself is not enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial." *Id.* at 127-28.

This aggregation principle remains a cornerstone of Commerce Clause jurisprudence. *E.g.*, *Lopez*, 514 U.S. at 558 ("'[W]here *a general regulatory statute bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under that statute is of no consequence.'") (quoting *Maryland v. Wirtz*, 392 U.S. 183, 196 n. 27 (1968)); *Fry v. United States*, 421 U.S. 542, 547 (1975) (same). To be sure, the Court has raised the possibility of limiting aggregation to economic activity. *See Morrison*, 529 U.S. at 613 ("[W]e need not adopt a categorical rule against aggregating the effects of any noneconomic activity in order to decide these cases."). But there can be no doubt that the aggregation principle applies to

the production and distribution of a valuable commodity such as marijuana, activities that are plainly economic.

When viewed in the aggregate, the intrastate cultivation or distribution of marijuana substantially affects interstate commerce, for much the same reason as the local cultivation and consumption of wheat does. The *Wickard* Court concluded that homegrown wheat could substantially affect interstate commerce because it could displace wheat that would otherwise be purchased in interstate commerce. *Wickard*, 317 U.S. at 128 (homegrown wheat "supplies a need of the man who grew it which would otherwise be reflected by purchases in the open market"). In the same way, locally grown marijuana expands the total national supply of the drug and substantially affects marijuana in interstate trade by freeing up an equivalent amount for use by others. Congress rationally could have concluded that, in the aggregate, unregulated homegrown marijuana would substantially affect the national market for this substance, and that banning local cultivation and distribution will significantly reduce the overall supply.

Lopez and *Morrison* are easily distinguished from the case at hand because the federal programs in those cases had nothing to do with any sort of economic enterprise. *Lopez* involved federal regulation of the mere possession of guns near schools, which the Court concluded "is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce." *Lopez*, 514 U.S. at 567; *accord id.* at 580 (Kennedy, J., joined by O'Connor, J., concurring) ("[N]either the purposes nor the design of the statute has an evident commercial nexus."). Indeed, given that the gun possession ban applied only within 1000 feet of a school, the Court emphasized that the ban was "not an essential

part of a larger regulation of economic activity, in which the regulatory scheme would be undercut unless the intrastate activity were regulated." *Id.* at 561. Similarly, the regulated activity in *Morrison*, gender-related violence, is "not, in any sense of the phrase, economic activity." *Morrison*, 529 U.S. at 613. The *Morrison* Court reaffirmed that the noneconomic nature of the regulated conduct was "central" to both *Morrison* and *Lopez*. *Id.* at 610.

In contrast, the Controlled Substances Act targets the cultivation and distribution of a valuable commodity, activities that are indisputably economic. That the distribution might occur for free is of no consequence, just as the absence of any sale was of no consequence in *Wickard*, because even the free distribution of a commodity still constitutes economic activity and thus should be subject to aggregation. *See Lopez*, 514 U.S. at 556, 559-60 (describing the "production and consumption of homegrown wheat" in *Wickard* as economic activity even "'though it may not be regarded as commerce'") (quoting *Wickard*).

The federal controls at issue here raise none of the concerns that troubled the Court in *Lopez* and *Morrison*. For example, the Court viewed the government's position in those cases – particularly its proffered chain of causation between the regulated activity and interstate commerce – as so fatally attenuated as to threaten the elimination of all limits on federal power. *See Lopez*, 514 U.S. at 564 ("[I]f we were to accept the Government's arguments, we are hard pressed to posit any activity by an individual that Congress is without power to regulate."); *Morrison*, 529 U.S. at 615 ("Congress' findings are substantially weakened by the fact that they rely so heavily on a method of reasoning that we have already rejected as

unworkable if we are to maintain the Constitution's enumeration of powers.").

In contrast, the findings supporting the Controlled Substances Act are direct and commonsensical, rooted in the eminently reasonable notion that law enforcement authorities cannot distinguish between drugs based on whether they have traveled intrastate or interstate, and that locally produced drugs add to the overall national supply in a harmful way. 21 U.S.C. §§ 801(3)-(6). They do not "pile inference upon inference in a manner that would bid fair to convert congressional authority under the Commerce Clause to a general police power." *Lopez*, 514 U.S. at 567. Rather, they suggest only the reasonable conclusion that when Congress seeks to control interstate traffic in a particular commodity, it may regulate the intrastate cultivation or distribution of that commodity where it is infeasible to distinguish between the two, and where intrastate production and distribution substantially affect interstate traffic.

II. CONGRESS MAY REGULATE THE INTRASTATE CULTIVATION OR DISTRIBUTION OF MARIJUANA AS PART OF A CLASS OF ACTIVITY THAT SUBSTANTIALLY AFFECTS INTERSTATE COMMERCE.

A. Congress May Regulate All Marijuana Cultivation and Distribution As a Class.

A second line of Commerce Clause cases provides additional support for petitioners by authorizing Congress to address an entire "class of activity" without establishing exceptions for individual intrastate applications. In *Perez v. United States*, 402 U.S. 146 (1971), the Court upheld a

criminal statute prohibiting extortionate credit transactions even though the law did not require any showing by the prosecution that the transaction resulted in the interstate movement of goods, involved the use of the facilities of interstate commerce, or affected interstate commerce. Rather, the *Perez* Court stressed that Congress could rationally conclude that extortion as a class of activity affects interstate commerce. *Id.* at 154-55. The Court could not have been clearer: "Where the class of activities is regulated and that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class." *Id.* at 154 (quoting *Maryland v. Wirtz*, 392 U.S. 183, 193 (1968)).

The *Perez* Court held that Congress rationally could conclude that loan sharking provides organized crime with a lucrative source of revenue, allows organized crime to launder money obtained through illegal gambling and narcotics rackets, and leads to the takeover of legitimate businesses. *Id.* at 155-57. Because Congress had authority to regulate the overall class of activity that comprises extortionate credit transactions, it made no difference whether the particular extortion carried out by Perez affected interstate commerce.

The Court also used this "class of activity" analysis in *Wirtz* to uphold the application of federal wage and hour controls on employees of hospitals, schools, and similar enterprises, even though the employees had no direct connection to interstate commerce. *Wirtz*, 392 U.S. at 193. The *Wirtz* Court emphasized that when Congress exercises its power to declare that an entire class of activity substantially affects commerce, "[t]he only question for the courts is then whether the class is 'within the reach of the federal power.'" *Id.* at 192 (citation omitted).

Since *Lopez*, federal courts have continued to rely on the *Perez* "class of activity" doctrine to sustain a variety of federal laws.[2] Because Congress could rationally conclude that the cultivation and distribution of marijuana as a class of activity substantially affects interstate commerce, it may regulate the entire class, and courts should not excise individual instances of intrastate activity.

To be sure, Congress should not be allowed to circumvent established precedent and regulate activity that falls outside its constitutional authority through the simple expedient of attaching federal controls to otherwise permissible regulation. For example, Congress could not resurrect the provisions struck down in *Lopez* and *Morrison* by

[2] *E.g.*, *United States v. Holston*, 343 F.3d 83, 90-91 (2d Cir. 2003) (upholding conviction under federal child pornography law, notwithstanding failure to prove defendant intended to sell it, because when Congress regulates a class of activities that substantially affect interstate commerce, "[t]he government need not demonstrate a nexus to interstate commerce in every prosecution"); *United States v. Turner*, 301 F.3d 541, 547-48 (7th Cir. 2002) (upholding conviction under federal law that prohibits employees from embezzling from insurance companies even if defendant's actions did not affect interstate commerce, because "we look to the 'class of activities' and determine their 'total incidence' on interstate commerce") (quoting *Perez* and *Wirtz*), *cert. denied*, 537 U.S. 1077 (2002); *United States v. Cortes*, 299 F.3d 1030, 1036 (9th Cir. 2002) (upholding application of federal carjacking law because carjacking as a class of activity affects interstate commerce, regardless of whether a particular instance has a trivial effect), *cert. denied*, 537 U.S. 1224 (2003); *Navegar, Inc. v. United States*, 192 F.3d 1050, 1061 n.7 (D.C. Cir. 1999) (Congress may ban intrastate possession of semiautomatic assault weapons as part of a broad prohibition on any manufacture, transfer, or possession because the class of activity affects interstate commerce, citing *Perez*); *United States v. Olin*, 107 F.3d 1506, 1509-11 (11th Cir. 1997) (upholding application of federal toxic waste cleanup requirements, notwithstanding absence of evidence that waste caused off-site damage, because the class of regulated activity substantially affects interstate commerce).

reenacting them as part of an interstate transportation bill and deeming the resulting jumble of unrelated provisions a "class" of activity. But where Congress addresses a rationally unified class of activity that substantially affects interstate commerce, such as drug traffic, longstanding precedent precludes the courts from redacting individual intrastate applications out of the federal program.

B. Congress May Regulate All Marijuana Cultivation and Distribution As a Class To Promote Adequate Enforcement.

The "class of activity" line of authority applies with particular force where regulation of the entire class is necessary to ensure adequate enforcement. The Court long has recognized that "where the interstate and intrastate aspects of commerce were so mingled together that full regulation of interstate commerce required incidental regulation of intrastate commerce, the Commerce Clause authorized such regulation." *Lopez*, 514 U.S. at 554 (citing *Shreveport Rate Cases*, 234 U.S. 342 (1914)). As noted above, the *Lopez* Court stressed that the limited gun ban before it, which applied only within 1000 feet of schools, was "not an essential part of a larger regulation of economic activity, in which the regulatory scheme would be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561. The *Shreveport Rate Cases*, in turn, discuss several other cases sustaining congressional regulation of intrastate activity where necessary to control interstate commerce. *See Shreveport Rate Cases*, 234 U.S. at 352-53.

Here, Congress reasonably found that the regulation of the intrastate incidents of drug traffic is "essential" to

the effective control of interstate drug trade. 21 U.S.C. § 801(6). Although "Congress normally is not required to make formal findings" supporting its assertion of Commerce Clause authority, *Lopez*, 514 U.S. at 562, the Controlled Substances Act contains extensive congressional findings on how controlled substances produced or distributed intrastate are indistinguishable from those in interstate commerce and thus, if left unregulated, would undermine law enforcement efforts to control interstate drug trade. Specifically, Congress found that "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate." 21 U.S.C. § 801(5). Congress also reasonably found that local manufacture and distribution of these fungible products can easily lead to interstate transport. *Id.* at § 801(4). As a result, "[f]ederal control of the intrastate incidents of the traffic in controlled substances is *essential* to the effective control of the interstate incidents of such traffic." *Id.* § 801(6) (emphasis added).

The Court repeatedly has relied on the inability to distinguish intrastate from interstate activity to uphold federal laws that regulate both together. *See, e.g., Currin v. Wallace*, 306 U.S. 1, 11 (1939) (Congress may regulate intrastate and interstate transactions in the tobacco market where transactions were conducted "in a manner which made it necessary, if the congressional rule were to be applied, to make it govern all the tobacco thus offered for sale"); *Shreveport Rate Cases*, 234 U.S. at 351-52 ("Wherever the interstate and intrastate transactions of

carriers are so related that the government of the one involves the control of the other, it is Congress, and not the state, that is entitled to prescribe the final and dominant rule.").

The use of marijuana for medical, as opposed to recreational, reasons does not change the analysis. Creating an exception for medical use could undermine enforcement efforts by imposing an often difficult burden on prosecutors of establishing the violator's subjective motivation and intent beyond a reasonable doubt. Given that marijuana used in response to medical ailments is not readily distinguishable from marijuana used for other reasons, Congress rationally concluded that the control of all use is necessary to address the national market for controlled substances.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

ANGEL MCCLARY RAICH, ET AL.,

Respondents.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF CONSTITUTIONAL LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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October 13, 2004

Question Presented

Whether the Controlled Substances Act, 21 U.S.C. §801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate possession and manufacture of cannabis for personal medical use.

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Interest of the Amici Curiae

Amici are scholars who teach and write about constitutional law, with a particular interest in constitutional federalism.[1] Steven Calabresi is George C. Dix Professor of Constitutional Law at Northwestern University School of Law, where he also teaches Comparative Law. Charles Fried is Beneficial Professor of Law at Harvard Law School, where he teaches Constitutional Law. Douglas Laycock is Alice McKean Young Regents Chair in Law at the University of Texas at Austin, where he teaches Constitutional Law. David Shapiro is William Nelson Cromwell Professor of Law at Harvard Law School, where he teaches Federal Courts. Ilya Somin is Assistant Professor of Law at George Mason University School of Law, where he teaches Constitutional Law. Ernest A. Young is Judge Benjamin H. Powell Professor of Law at the University of Texas at Austin, where he teaches Constitutional Law and Federal Courts. Each of us has written extensively about federalism.[2]

The signatories of this brief represent a wide variety of perspectives on what Congress may do under the Commerce Clause. But we all agree that some activities must be beyond the reach of the commerce power, and that the Government's position here is inconsistent with that structural limit. If Congress can regulate

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[1] Pursuant to Supreme Court Rule 37.6, counsel for the *amici* certifies that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than the *amici* or their counsel has made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.3(a), letters of consent from both parties to the filing of this brief have been filed with the Clerk.

[2] We file this brief in our personal capacities as scholars; none of our respective universities takes any position on the issues in this case. We emphasize that each of the *amici* signing this brief has participated in the drafting of it. This is not always the case with academic briefs.

household production for household consumption, then the Commerce Clause can reach the most intimate human relationships and activities. Despite widespread disagreements in the academy about the contours of federalism doctrine, scholars from many perspectives can agree that *this* case involves an undue extension of federal authority. And we can agree on an approach to the Commerce Clause that imposes meaningful and judicially-enforceable limits on national authority while still allowing very broad scope for national action.

Summary of Argument

This is a critical case for the Court's Commerce Clause jurisprudence. *United States v. Lopez*, 514 U.S. 549 (1995), demonstrated, for the first time since 1937, that the Commerce Clause has enforceable limits. And *United States v. Morrison*, 529 U.S. 598 (2000), entrenched the principle that Congress may not regulate acts that are noncommercial in character. But two doctrinal routes remain open to rob that principle of any force. One is to define the regulated "act" at such a high level of generality that it will always include some commercial applications. The other is to characterize every regulation of *noncommercial* activity as "an essential part of a larger regulation of economic activity." *Lopez*, 514 U.S. at 561. Both possibilities are open in this case. Unless the Court develops meaningful limits on each, *Lopez* and *Morrison* will be left as hollow shells.

The Government in this case has made the same error that it made in *Lopez* and *Morrison*: It has written a strong brief about what it *can* do, without leaving any room under its theory of the Commerce Clause for what it *cannot* do. The Commerce Clause has very broad scope, but there must be a limit. In *Lopez* and *Morrison*, the Government unsuccessfully defended a view of "substantial effects" on interstate commerce that, by "piling inference upon inference," *Lopez*, 514 U.S. at 567, stripped the Commerce Clause of any meaningful limit. The Government's

position in the present case is different in form but identical in result. The Government insists that the relevant regulated act for determining whether the regulation is commercial or noncommercial in character is "the overall class of activities covered by the [Controlled Substances Act]—the manufacture, distribution, and possession of controlled substances." Pet. Br. 36. But there are hardly any activities that Congress might seek to regulate that cannot be squeezed into a sufficiently general category that also includes commercial acts. Likewise, the Government insists not only that its regulation of noncommercial medical uses is part of a "comprehensive scheme" for regulating the commercial marijuana market, but that the courts must accept this assertion of necessity without any clear statement by Congress or factual foundation in the record. Needless to say, similar comprehensive scheme arguments could have been made in *Lopez* and *Morrison*, and if this Court reverses the Ninth Circuit, those arguments *will* be made in future to uphold any regulation that Congress might conceivably wish to undertake.

Judicial review is appropriate in Commerce Clause cases, notwithstanding the existence of political checks on national action. Such review, moreover, should not be so deferential to Congress as to amount to a rubber stamp. The practice of federal systems around the world belies the apparently widespread perception that judicial review of federalism issues is somehow unusual. On the contrary, the constitutional courts of Canada, Australia, Germany, and the European Union enforce limits on central power.

Viable doctrinal instruments are available to limit both the level of generality and comprehensive scheme problems under the Commerce Clause. The level of generality issue is actually a red herring, prompted by a common misinterpretation of *Wickard v. Filburn*, 317 U.S. 111 (1942), as involving noncommercial activity. The proper approach is simply to ask whether the *specific* activity subjected to federal regulation in the particular case is commercial

in nature. This case involves, after all, a challenge to the Controlled Substances Act *as applied* to Respondents' conduct. In any event, we think the considered decisions of Congress, California, and other states to regulate medical uses of drugs differently from nonmedical uses militates strongly in favor of evaluating the case at the lower level of generality.

Likewise, limiting principles can preserve an exception to *Lopez* and *Morrison* for regulation of noncommercial activity that is truly "essential" to a comprehensive federal regulatory scheme, without gutting the significance of those cases. Specifically, we argue that the Government should have to demonstrate that its judgment of necessity is plausible, that it has been clearly stated by Congress, and that it has an adequate foundation in the record. This approach hardly forecloses significant deference to Congress, but the Government has made no such showing here.

Argument

I. This Court should enforce limits on national authority under the Commerce Clause.

Federalism is one of the few areas of constitutional law where there is continuing debate about whether the relevant constitutional norms should be enforced by courts. While the signatories to this brief disagree on the extent to which certain aspects of federalism should be enforced through judicial review, we all agree that the Commerce Clause is one of the clear cases where judicial action is appropriate. To say this is neither to disregard "the political safeguards of federalism," Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 COLUM. L. REV. 543 (1954), nor to urge that courts play a *primary* role in limiting national power. But this Court should not refuse to enforce the doctrine of enumerated powers or, what is much the same thing, apply a standard of review so deferential as to impose no

meaningful check. Moreover, to the admittedly contested extent that the practice of other nations is relevant, the boundary-enforcing role contemplated for courts in *Lopez* and *Morrison* is consistent with the role of courts in other federal systems around the world.

A. Cases concerning the limits of Congress's enumerated powers should not be left exclusively to the "political safeguards of federalism."

An intellectual tradition stretching back to James Madison's essays in The Federalist[3] emphasizes the States' representation in Congress as a check on national policies that threaten state prerogatives. But virtually all of that tradition's exponents – including Justice Blackmun, in his opinion for the Court in *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 550-51 (1985) – have emphasized "political safeguards" primarily as an argument against non-textual limits on national authority that operate *within* the scope of Congress's enumerated powers. *Garcia* drew a sharp distinction between judge-made limits like the *National League of Cities* doctrine and the boundaries of the enumerated powers set forth in Article I:

> *Apart from the limitation on federal authority inherent in the delegated nature of Congress' Article I powers*, the principal means chosen by the Framers to ensure the role of the States in the federal system lie in the structure of the Federal Government itself. *Id.* at 550 (emphasis added).

Other proponents of political checks have likewise reaffirmed the notion of enforceable limits on the enumerated powers.[4]

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[3] *See* The Federalist Nos. 45 & 46 (James Madison) (Clinton Rossiter, ed., 1961).

[4] Professor Wechsler argued that "the Court is on weakest ground when it opposes its interpretation of the Constitution to that of Congress in the interests of the

To say that courts must enforce the limits of Congress's Article I powers is not, of course, to resolve how strict those limits should be. And the efficacy of non-judicial checks may well be relevant to the question of how much deference the Court should accord to Congress's judgments in support of commercial legislation. The case for a deferential standard of review has been undermined, however, by a broad body of scholarship, encompassing commentators of all ideological predispositions, criticizing the efficacy of the states' representation in Congress as a check on national aggrandizement.[5] In particular, many scholars have concluded that national politicians are likely to view state politicians as competitors rather than allies whose prerogatives are to be guarded from national encroachment.[6] Even more important, this Court has held, after extended consideration, that Members of Congress are *not* representatives of their state governments, but rather have a direct obligation to represent their constituents that is not mediated through state institutions. *See U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 821-22 (1995).

Our point is not that the "political safeguards of federalism" are always ineffectual, or even that judges are the *primary* guardians of state autonomy. Indeed, the inherent limitations on judicial review mean that states must rely on political checks to constrain national action on most issues, most of the time. The question is whether the judicial standard for evaluating Commerce Clause legislation should be so deferential as to entrust Congress with complete discretion. The basic point of *Lopez* and *Morrison* is this: If one proposes a form of Commerce Clause analysis under which one cannot imagine an act that would exceed Congress's authority, then that analysis must be wrong. This is particularly true in a case, like this one, where the issue of who may regulate implicates important human values – here, the choice of means to escape pain and suffering.

The balance to be struck – between undue judicial activism and abdication of the Court's responsibility – is difficult and delicate. Clearly *some* deference to congressional judgments is appropriate. But at the same time the Court may properly insist that those

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states . . . ." Wechsler, *supra*, at 559. But immediately before the sentence just quoted, Wechsler acknowledged that "[t]his is not to say that the Court can decline to measure national enactments by the Constitution when it is called upon to face the question in the course of ordinary litigation; the supremacy clause governs there as well." *Id.* We read this passage as plainly distancing Wechsler from any sort of judicial abdication in enumerated powers cases.

Likewise, James Madison's discussion of political safeguards in Federalist 45 emphasized that "[t]he powers delegated by the proposed Constitution to the Federal Government, are few and defined." Federalist No. 45, *supra*, at 292. And Chief Justice Marshall's statement in *Gibbons v. Ogden*, 9 Wheat. (22 U.S.) 1 (1824), that "the sole restraints" on Congress's power are "[t]he wisdom and the discretion of Congress . . . and the influence which their constituents possess" presupposed that the exercise of power was "limited to specified objects" such as "commerce . . . among the several States." *Id.* at 197.

[5] The leading advocate of "political safeguards" today concedes that "Wechsler's theory is under siege," and that "subsequent experience and later developments have robbed his analysis of much, if not all, of its force." Larry D. Kramer, *Putting the Politics Back Into the Political Safeguards of Federalism*, 100 COLUM. L. REV. 215, 218 (2000). Dean Kramer proposes a new version of "political safeguards" that relies on the operation of political parties and bureaucratic personnel to tie the interests of state and national policymakers together. *See id.* at 278-87. That theory has prompted searching criticism, *see, e.g.*, Saikrishna B. Prakash & John C. Yoo, *The Puzzling Persistence of Process-Based Federalism Theories*, 79 TEX. L. REV. 1459 (2001); Lynn A. Baker & Ernest A. Young, *Federalism and the Double Standard of Judicial Review*, 51 DUKE L.J. 75, 112-117 (2001), and it has not gained anything approaching the widespread acceptance that Wechsler's account once commanded.

[6] *See, e.g.*, Baker & Young, *supra*, at 113-14; Barry Friedman, *Valuing Federalism*, 82 MINN. L. REV. 317, 374-75 (1997); Clayton P. Gillette, *The Exercise of Trumps by Decentralized Governments*, 83 VA. L. REV. 1347, 1357 (1997); Larry Kramer, *Understanding Federalism*, 47 VAND. L. REV. 1485, 1510-11 (1994).

judgments fall within broad but not undefined limits – that Congress's judgments have an adequate foundation and that they be clearly stated. "To make political safeguards of federalism work, some sense of enforceable lines must linger." Vicki Jackson, *Federalism and the Uses and Limits of Law:* Printz *and Principle?* 111 HARV. L. REV. 2180, 2228 (1998).

Finally, we submit that judges are not free to pick and choose which portions of the Constitution they will enforce, and that a decision to yield to the political process must be reconciled, in a principled way, with decisions to engage in more searching judicial review in other areas. The courts have enforced separation of powers principles, as well as "dormant" commerce limits on *state* regulation, notwithstanding the operation of strong "political safeguards" in those areas.[7] Objections to judicial enforcement of federalism have often sounded in judicial competence and the difficulty of formulating manageable judicial standards for limiting Congress's power. But similar competence objections have been rejected in areas posing comparable or even greater difficulties.[8]

The constitutional text plainly envisions the Commerce Clause as a binding limit on Congress. Chief Justice Marshall recognized that "should Congress . . . pass laws for the accomplishment of objects not entrusted to the government; it would become the painful duty of this tribunal . . . to say that such an act was not the law of the land." *McCulloch v. Maryland*, 4 Wheat. (17 U.S.) 316, 423 (1819). "For the Court to declare, or be understood to declare, that 'federalism' limits are not judicially enforceable, creates a

[7] *See, e.g., Clinton v. City of New York*, 524 U.S. 417 (1998); *Fulton Corp. v. Faulkner*, 516 U.S. 325 (1996).

[8] *See, e.g., Lawrence v. Texas*, 539 U.S. 558 (2003); *Baker v. Carr*, 369 U.S. 186 (1962); *see also Washington v. Glucksberg*, 521 U.S. 702, 765-73 (1997) (Souter, J., concurring in the judgment)

serious dissonance with understandings of the rule of law under American constitutionalism." Jackson, *supra*, at 2224.

B. Constitutional courts in federal systems around the world decide cases concerning the allocation of authority between the national and sub-national authorities.

Reluctance to enforce at least some aspects of federalism through judicial review is puzzling in light of comparative practice around the globe. Most federal systems envision a judicial role in the enforcement of constitutional boundaries between national and subnational authority. Indeed, this pattern is so prevalent that some European commentators have incorporated it into the very definition of federalism. Judge Koen Lenaerts, for instance, has stated that "[f]ederalism is present whenever a divided sovereign is guaranteed by a national or supranational constitution *and umpired by the supreme court of the common legal order*." Koen Lenaerts, *Constitutionalism and the Many Faces of Federalism*, 38 AM. J. COMP. L. 205, 263 (1990) (emphasis added).[9]

The European Court of Justice has long played a leading role in defining the balance between the European Union (and its predecessor, the European Community) and its Member States. Although for much of its history, the ECJ worked primarily to consolidate the Community's authority, it recently held that a Community directive exceeded the competence granted to the Community under its constitutive treaties. *See* Case C-376/98, Germany v. Parliament and Council (Tobacco Advertising), 2000 E.C.R. I-8419, [2000] C.M.L.R. 1175 (2000). In Germany, the Federal Constitutional Court is specifically empowered by statute to review disputes about the allocation of power between the national government and the Lander. That court recently ruled "in favor of

[9] *See also* Martin Shapiro, *The European Court of Justice*, in THE EVOLUTION OF EU LAW 321 (Paul Craig & Grainne de Burca eds., 1999).

strict judicial scrutiny of the requirements of Article 72, para. 2," which is the rough German equivalent of our Necessary and Proper Clause. Markus Rau, *Subsidiarity and Judicial Review in German Federalism: The Decision of the Federal Constitutional Court in the* Geriatric Nursing Act *Case*, 4 GERMAN L. 223, 223-24 (2003).

The Supreme Court of Canada enjoys statutory authority to hear cases concerning the powers of the national parliament, Supreme Court Act, R.S. ch. 8 § 53(1)(d) (1990), and it has affirmed that "it is the high duty of this court to insure that the legislatures do not transgress the limits of their constitutional mandate." *Amax Potash Ltd. v. Saskatchewan*, 2 SCR 576 (1976). The Australian High Court has similarly insisted that "upon the judicature rested the ultimate responsibility for the maintenance and enforcement of the boundaries within which governmental power might be exercised." *Ex Parte Boilermakers' Society of Australia*, 94 CLR 254 (1956). More recently, that court reaffirmed that "[t]he federal judiciary is responsible for determining the ambit of federal power." *Re Wakim*, 198 CLR 511 (1999).

There are important differences between these federal systems and our own, and one should hesitate before concluding that any particular rule or doctrine could be imported from one system to another. The point is simply that many federal systems accept and rely on judicial review as an important component of the structure. The proposition that *American* courts have an appropriate role to play in enforcing the boundaries of national power is typical rather than anomalous as a matter of comparative law.

II. Properly defined, the regulated activity in this case is not commercial in nature.

This case raises two unresolved questions under this Court's Commerce Clause cases. *Lopez* and *Morrison* held that Congress may regulate individual activities that substantially affect interstate commerce only in the aggregate, but only when the regulated

activity is commercial in nature. *See United States v. Morrison*, 529 U.S. 598, 613 (2000); *United States v. Lopez*, 514 U.S. 549, 560-61, 567 (1995). The first key issue in the present case thus concerns how to define the regulated activity for purposes of this rule. The second issue arises from *Lopez*'s suggestion that Congress may regulate noncommercial acts when such regulation is "an essential part of a larger regulation of economic activity." 514 U.S. at 561. We deal with the former issue in this Part, the latter in Part III.

The most difficult aspect of this Court's distinction between commercial and noncommercial activity involves fixing the level of generality at which to evaluate the regulated activity. In this case, possession of marijuana generally may be an integral part of commercial activity, but possession solely for medical purposes as defined by California law is not. The appropriate analysis should focus on the specific activity engaged in by Respondents. On close examination, that is what this Court's precedents require; moreover, it is a more readily administrable rule than the alternatives.

If this Court elects to pursue a more open-ended analysis, the more specific level of generality is nevertheless the right one in this case. Choosing the "correct" level of generality is not easy, but it is made less difficult in this case by a crucial fact: Both Congress and California, as well as at least 15 other states, have chosen to regulate medical uses of drugs differently than non-medical uses. The Court should defer to that judgment and evaluate the constitutionality of the Controlled Substance Act specifically as it applies to the medical use of cannabis.

A. The correct analysis focuses on the specific activity before the Court in a particular case.

Wickard v. Filburn held that Congress may regulate activities that, considered individually, have minute effects on the national economy so long as, considered in the aggregate, the class of similar acts substantially affects interstate commerce. 317 U.S. 111, 125

(1942). Because virtually any conceivable human activity affects such commerce in the aggregate, *Wickard*'s aggregation analysis had the potential to remove all limits on Congress's authority. *Lopez* and *Morrison* were careful to insist that aggregation is only available where the regulated activity is itself commercial in nature. That move, however, raised the question whether the wheat production in *Wickard* was itself "commercial." The most common explanation is that while Filburn's own activity may *not* have been commercial – it is asserted that his wheat went simply to feed his family – it was part of a larger class of activity which is *usually* conducted for commercial purposes. *See* Pet. Br. 37.

This faulty account gives rise to the level of generality problem in this case. The Ninth Circuit majority asked whether possession of medical cannabis that has not been bought or sold – the class of activity carved out by California's medical use exemption – is commercial, and it answered that question in the negative. *See Raich v. Ashcroft*, 352 F.3d 1222, 1228 (9th Cir. 2003). Judge Beam's dissent, on the other hand, asked whether marijuana consumption *in general* is commercial; unsurprisingly, he reached a different conclusion from that of the majority. *See id.* at 1238-39 (Beam, J., dissenting). These contrary results demonstrate, unfortunately, that judicial attempts to determine whether the general or the specific frame of reference "fits" better in any given case are likely to be subjective and unpredictable.

The Court can and should avoid this sort of indeterminate analysis, because the usual explanation for *Wickard* is wrong. Filburn's practice was "to sell a portion of his crop; to feed part to poultry and livestock on the farm, some of which is sold; to use some in making flour for home consumption; and to keep the rest for the following seeding." 317 U.S. at 114. The sale of part of the crop, and the sale of the poultry and livestock fed on the wheat, were commercial activities in the ordinary sense. Seeding the next year's crop for the same purposes was part of the cycle of

commercial production. Only the wheat made into flour for home consumption was not sold in either its original or changed form. Moreover, the law at issue reached Filburn's wheat only because he disposed of it "by feeding in any form to poultry or livestock which, or the products of which, are sold, bartered, or exchanged, or to be so disposed of." *Id.* at 118-19. Thus, the government regulated Filburn because he sold the livestock that ate the wheat – not because he fed part of it to his family. Read in light of the facts and regulation actually at issue, the "consumption" in *Wickard* was consumption of raw materials for commercial production.

The specific activity giving rise to the prosecution in *Wickard* was thus commercial in its own right without any recourse to a broader class of activity. *Wickard* is not authority for analyzing the regulated activity at a higher level of generality, as the Government would have this Court do. The Court need not "choose" a level of generality; it should simply ask whether Respondents' own activities were commercial in nature.

Analyzing the case at a broader level of generality that does not reflect the facts would make the commerce power exceptionally difficult to limit. As Justice Thomas observed in *Lopez*, "one always can draw the circle broadly enough to cover an activity that, when taken in isolation, would not have substantial effects on commerce." 514 U.S. at 560 (Thomas, J., concurring). The Government's approach would mean that Congress could lump any non-market form of production in with production for market, so as to regulate the entire class. Congress could regulate the growing of geraniums in window boxes, where no sale or purchase ever takes place, simply because such activity falls within a broader class of "agricultural production" that also includes growing products for sale. Indeed, every form of household production is potentially a substitute for purchasing goods and services in a commercial transaction. Parents who cook dinner, clean house, and care for their children might instead have gone to a restaurant, hired a

cleaning service, or used a daycare center. Doing these chores for oneself is no doubt production, and no doubt has economic value; and all the parents who perform these chores for themselves no doubt have, in the aggregate, a substantial impact on the demand for commercial substitutes. But surely Congress cannot regulate these household chores under the commerce power. The Government cannot win this case simply by characterizing the growing of cannabis within the home as production.

The Court might try to prevent this sort of expansion by "choosing" the appropriate level of generality in a way that would limit the clause's scope, but we fear that endeavor would cast this Court adrift on a sea of difficulties. Virtually all activities can be evaluated at various levels of generality, as this Court's debates about the right to privacy have demonstrated.[10] In most cases, it will be extremely hard for courts to give a principled reason that one level of generality "fits better" than another. A far more determinate analysis will result from simply analyzing the activity actually presented to the Court in a concrete case.

This approach is consistent with the traditional distinction between as-applied and facial challenges. If Respondents had challenged the Controlled Substances Act on its face, then it would surely be appropriate to evaluate the commercial nature of the overall class of activity covered by the statute. The question before the Court, after all, would be whether the CSA has *any* (or at least a significant class of) constitutional applications. *See United States v. Salerno*, 481 U.S. 739, 745 (1987). But Respondents have instead challenged the act as applied to them; it thus makes sense to ask

[10] *Compare, e.g., Bowers v. Hardwick*, 478 U.S. 186, 190 (1986) (defining the right in question as a right to commit homosexual sodomy), *with id.* at 199 (Blackmun, J., dissenting) (defining the right in question as a right of privacy in intimate personal relationships); *Michael H. v. Gerald D.*, 491 U.S. 110, 124-27 (1989), *with id.* at 141-42 (Brennan, J., dissenting).

whether *their* activity – growing their own cannabis for medical purposes without any buying or selling – is commercial. The Government's position in effect insists that Congress's acts are immune to as-applied challenges and that Respondents can only make a facial challenge to the CSA. That, however, contradicts the well-established teaching in this Court's cases that as-applied challenges are the norm. *See, e.g., United States v. Raines*, 362 U.S. 17, 20-22 (1960).

It is also important to distinguish the level of generality issue from *Wickard*'s key holding that a "substantial effect" on interstate commerce may be shown by aggregating the effects of individual acts. The prerequisite to aggregation is a showing that the regulated activity is itself "commercial" in nature, and the relevant activity for that purpose is the specific conduct of the person challenging the law. That argument is entirely consistent with aggregating the effects of many similar actions, for purposes of determining "substantial effect," if the action at issue is shown to be commercial. In this case, for instance, the Government must show that medical use of cannabis that is neither bought nor sold is "commercial"; if it can do so, then the Court should consider whether the aggregate effect of many such medical uses on commerce would be substantial.

Nor would adopting an as-applied analysis necessarily commit this Court to striking down federal restrictions on possession of drugs (or other items) anytime that the Government cannot show a prior or ultimate sale in the particular case. Many possession restrictions are justifiable as part of a "comprehensive scheme" of federal regulation aimed at commercial markets. That, of course, is the Government's other central argument in this case. *See infra* Part III. The practical reasons that Congress may want to reach noncommercial acts – like possession divorced from sale – are best dealt with under the "comprehensive scheme" rubric, which

emphasizes practical concerns, rather than by artificial conceptual expansion of the regulated activity at issue.

The "level of generality" analysis should stop here: Having challenged the CSA as applied to them, Respondents need show only that *their* activity is noncommercial in nature, whether or not the CSA may have constitutional applications to commercial activities in other contexts.

B. Medical uses of drugs are sufficiently distinct from non-medical ones to require separate analysis under the Commerce Clause.

Even if the Court pursues a more open-ended analysis, we think the "right" level of generality in this case is the more specific one. Congress has chosen, throughout the Controlled Substances Act, to treat medical uses distinctly from non-medical uses; so have the other eight states that permit medical cannabis use and others that have taken steps in that direction. *See* Resp. Br. 1 n.1. Even though these states and Congress disagree about whether cannabis itself has a valid medical use, they agree that valid medical uses – where they exist – are sufficiently distinct as to require separate treatment. Rather than "choose" a level of generality itself, this Court should defer to that consensus judgment.

The Government asserts that the relevant class of activities in this case involves "the overall class of activities covered by the CSA – the manufacture, distribution, and possession of controlled substances." Pet. Br. 36. As the Government acknowledges, the critical question under this approach is whether all forms of those activities are sufficiently similar that they "cannot be divorced from the general class of activities regulated by the CSA." *Id.* at 35-36.[11]

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[11] The Government also argues that, even if medical and non-medical uses are distinct classes of activity, the practical relationship between them requires that an effective regulatory scheme reach both. We consider that claim in Part III, *infra*.

Judge Pregerson correctly argued below for a narrower characterization of the relevant activity, 352 F.3d at 1228, but one need not rely on abstract analysis for that conclusion. Both the federal and the state statutory schemes reflect a judgment that medical and non-medical uses require distinct treatment.

It is important to distinguish between two questions. One is whether medical and non-medical uses are sufficiently similar, in terms of their bearing on *commerce*, to require unitary treatment. The second is whether cannabis *has* a legitimate medical use. There is a disagreement on the second question between Congress, which denies any medical applications for cannabis, and California and several other states, which believe such applications exist. But that should not obscure the basic agreement on the *first* question. The federal regulatory scheme, no less than the State's, treats medical uses differently from non-medical ones.

As the Government explains in its brief, drugs are listed in schedule I of the CSA if they have "'no currently accepted medical use.'" Pet. Br. 3 (quoting 21 U.S.C. § 812(b)(1)(B)). Drugs that do have such medical uses, however, are treated quite differently:

> [D]rugs listed in schedules II through V may be dispensed and prescribed for medical use. ManDufacturers, physicians, pharmacists and others who may lawfully produce, prescribe, or distribute drugs listed in schedules II through V must, however, comply with stringent statutory and regulatory provisions that control the manufacture and distribution of such drugs. 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306.

But such relationships often exist between highly varied sorts of activity. For example, the Government might plausibly contend that it cannot effectively regulate the market for illegal drugs without also regulating the content of drug education programs in schools, but no one would claim that such programs fall in the same class of activities as the illegal drug transactions themselves.

Pet. Br. 34. One of the basic reasons for differentiating between schedule I drugs and others is thus to treat medical uses differently from non-medical ones. True, Congress and California disagree about whether, in terms of the federal scheme, cannabis belongs on schedule I or somewhere on schedules II through V; Congress thinks that cannabis does not have a proper medical use, while California thinks it does. But this dispute of medical fact is not relevant to the key question of constitutional *power*, which turns on whether medical uses of a particular drug – if any there be – form a distinct class of activity from non-medical uses. The Controlled Substances Act reflects a judgment that they do.

Even if the federal scheme did not distinguish between medical and non-medical uses, however, it would remain relevant that a significant number of states, including California, view those classes of uses as sufficiently different to require separate treatment. That is not to suggest that the Court *must* defer to California's judgment that Congress may not constitutionally regulate medical cannabis; it is not even to say that California's choice should control the Court's analysis as to the appropriate level of generality at which to evaluate the case. But determining what constitutes a relevant class of activity for Commerce Clause purposes involves difficult judgments about the structure of regulation – judgments not easily made by courts. Where a government institution – like California and its eight sister states – has made a judgment on that question, that judgment ought to have some weight. The proposal to treat medical uses distinctly is not the *post hoc* rationale of a drug dealer's lawyer, but rather the regulatory policy of a sovereign state.

The primary objection to this sort of argument may be along the following lines: What is at issue in this case is the constitutionality of the *federal* statute; if that statute is within Congress's power, the position taken by *state law* on the same question is irrelevant. But our view is not that Congress's power depends on the position taken by state law; rather, we urge only that the state's considered

recognition of a distinct subset of the federally-regulated class ought to have some persuasive authority for a court trying to choose the appropriate analytical frame of reference. The whole notion of "political safeguards" for federalism announced by this Court in *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528 (1985), and reinforced in *Gregory v. Ashcroft*, 501 U.S. 452 (1991), is predicated on the *interaction* of state and national political actors. That model loses much of its vitality if courts must ignore the views of state institutions.

The Court should thus analyze whether the regulated activity, defined at the more specific level of medical use without any prior sale, is commercial. If it is *not*, then either of two different conclusions could plausibly follow. One is that Congress simply lacks power to regulate that subset of activity, and the statute is unconstitutional as applied. A second approach, however, would instead look back to the federal law and ask whether Congress specifically considered the narrower subset of activity and determined nonetheless to treat the broader class – here, all marijuana use – as a unitary activity.[12] This would be, in effect, a

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[12] This second approach would be analogous to this Court's decision in *Parker v. Brown*, 317 U.S. 341 (1943), which held that the Sherman Act did not apply to certain actions authorized pursuant to state law, even assuming that those actions would otherwise have been unlawful under the federal statute. The Sherman Act did not expressly reach conduct authorized under state law, and the Court was reluctant to impute any such intent to Congress, out of respect for the sovereign authority of the States. *See id.* at 350-51. *Parker* is not on all fours with this case, but it does support taking into account the content of state law and the nature of state interests when this Court construes a federal statute. This Court's extensive use of other clear statement rules in a variety of contexts likewise supports construing federal law with respect for state policies. *See, e.g.*, *Will v. Mich. Dept. of State Police*, 491 U.S. 58, 65 (1989) (statutes subjecting states to liability); *Pennhurst State School & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981) (spending conditions); *United States v. Bass*, 404 U.S. 336, 349-50 (1971) (federal regulation of traditionally state crimes).

clear statement rule that would presumptively interpret the more general federal statute not to reach the narrower subset of noncommercial uses. *Cf. Gregory*, 501 U.S. at 460-61.[13] If Congress *did* specifically state its judgment that medical and non-medical uses of drugs form a unitary class, then the commercial nature of the regulated act could be analyzed more generally. But the CSA supports the opposite reading.

The most compelling argument for the position offered here is the difficulty of the alternative. If the Court is to decide cases under the commercial/noncommercial distinction adopted in *Lopez* and *Morrison*, and if the Court eschews the simpler rule focusing on the specific conduct at issue in the case, then there is no escape from the need to define the class of activity being regulated. One might, of course, simply defer to Congress, but that would be tantamount to removing all limits on the Commerce Clause. Congress could override the results in *Lopez* and *Morrison*, for example, simply by regulating at the most general level of "guns" or "violent crime." If the reviewing court cannot look to the only other available external source – the policy choice embodied in state law – then the court will be thrown back on its own subjective judgments about the "best" level of generality at which to evaluate the case. That is no recipe for objectivity or predictability in the law.

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[13] This case raises serious statutory questions as to whether Congress meant to reach the specific activity at issue. *See* Resp. Br. 42-45. This Court had no occasion, in *United States v. Oakland Cannabis Buyers' Co-op*, 532 U.S. 483 (2001), to decide whether Congress intended to preclude a medical necessity defense asserted by *patients*, as opposed to those who supplied them with cannabis. *Id.* at 494. Deciding that question in the negative would not only accord with the presumption against preemption, *see Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), but also avoid the constitutional questions whether regulating such use exceeds the commerce power or infringes a due process right to pain relief, *see Washington v. Glucksberg*, 521 U.S. 702, 745 (1997) (Stevens, J., concurring in the judgment).

Finally, this approach has the virtue of distinguishing other difficult cases that currently seem headed to this Court in a way that reflects the underlying values associated with federalism. Considering a state's decision to define the relevant regulated act at a lower level of generality distinguishes those cases in which the state government has chosen to pursue a distinct policy choice from those in which it has expressed no policy interest. The former situation is much more likely than the latter to implicate the values of policy diversity and experimentation that this court has associated with federalism. *See Gregory*, 501 U.S. at 458.[14] In *United States v. McCoy*, 323 F.3d 1114 (9th Cir. 2003), for example, the Ninth Circuit has invalidated 18 U.S.C. § 2252(a)(4)(B), a statute prohibiting possession of child pornography, on the ground that it reaches acts that are noncommercial in nature. There is no evidence, however, that the State of California has recognized any distinct subclass of pornography as warranting different treatment – or, indeed, that California has expressed any interest in pornography that diverges from federal policy. There is no reason, then, to define the relevant act in that case at any level other than the general one selected by Congress. We of course take no position on the appropriate outcome in *McCoy*, should it reach this Court. Our point is simply that cases in which the state government has articulated a distinct policy of its own most directly implicate federalism's underlying values, and that a doctrinal analysis that takes those state policies into account is better able to track those values than one which does not.

At the end of the day, this case involves household production for household consumption, with no sales or prospect of sales. If the Government can regulate that, it can regulate anything. That is the narrowest ground of decision here.

---

[14] *See also* Susan R. Klein, *Independent-Norm Federalism in Criminal Law*, 90 CALIF. L. REV. 1541 (2002).

III. Regulation of medical cannabis is not "an essential part of a larger regulation of economic activity."

Even if the relevant act regulated by federal law is not itself commercial in nature, this Court has said that Congress may reach it if doing so is "an essential part of a larger regulation of economic activity." *Lopez*, 514 U.S. at 561. The Government has seized on this exception as a basis for regulating medical cannabis as part of a "comprehensive scheme" to restrict the trade in illicit drugs. The "comprehensive scheme" exception has the potential to swallow up the principle that Congress generally may not regulate noncommercial activities under the Commerce Clause. This case requires this Court to develop an account of the "comprehensive scheme" exception that does not lead to that result.

Two distinct limits on the "comprehensive scheme" exception may be extrapolated from this Court's decisions. The first focuses on process: *Congress*, not the Government's lawyers *post hoc*, should have to make the judgment of necessity, and that judgment should be clearly reflected in either the statute itself or the legislative record. The second limit is substantive: Congress's judgment that reaching noncommercial activity is necessary to a broader regulatory scheme should have an adequate foundation, as determined by the reviewing court. This determination should, and perhaps of necessity must, be deferential. But the court's analysis must not be so deferential as to foreclose meaningful review.

A. The "comprehensive scheme" exception must be narrowly construed.

The "comprehensive scheme" notion has its roots in decisions like the *Shreveport Rate Cases*, 234 U.S. 342 (1914), which recognized that sometimes subject matter within the Commerce Clause (there, railroad rates on traffic that crossed state lines) cannot be effectively be regulated without also reaching matter falling outside the Clause (e.g., railroad rates for *intra*state traffic). That

sort of judgment gives meaning to the Necessary and Proper Clause in Commerce Clause cases. The distinction in *Lopez* and *Morrison* between commercial and noncommercial activity already incorporates this principle to a much greater degree than did the Court's pre-1937 cases. After all, modern doctrine no longer distinguishes between *inter*state and *intra*state commerce, presumably on the theory that in an integrated national economy, the power to reach *intra*state commercial activity will almost always be necessary and proper to effective regulation of *inter*state commerce. The question is how much further this necessity principle is to be taken.

What seems principally to have divided the Court in *Lopez* and *Morrison* was the question whether noncommercial activity that "substantially affects" commerce can likewise be reached on a necessity rationale. The Government argued (and the dissenters agreed) in *Lopez* that the noncommercial act of bringing a gun to school must be regulated in order to protect the national economy from problems associated with poor schooling. *See* 514 U.S. at 563-64; *id.* at 620-22 (Breyer, J., dissenting). Likewise, in *Morrison*, the Government argued (and the dissenters agreed) that many forms of noncommercial violence against women must be regulable because they threaten the national economy, including efforts to regulate that economy so as to facilitate women's participation in it. *See* 529 U.S. at 615; *id.* at 634-36 (Souter, J., dissenting). The noncommercial acts in those cases surely had those effects, as a factual matter. The majority's answer instead was that *all* human activities have similar effects, and that to accept a pure "substantial effects" rule under modern conditions would leave the Commerce Clause without any limiting principle at all. *See Morrison*, 529 U.S. at 615-16; *Lopez*, 514 U.S. at 564.

A broad version of the "comprehensive scheme" exception would fatally undermine the resolution of this issue in *Lopez* and *Morrison*. At bottom, the Government's view of that exception is

simply a repackaged version of the claim that noncommercial acts can be regulated if they have *effects* on commercial ones. The Government argues, for example, that the existence of a legal use for cannabis would create problems of proof in establishing that any given marijuana cache seized by government officers was intended for *illegal* use. In other words, the noncommercial activity of home-grown medical use has an *effect* on the illegal market for marijuana, making that market harder to regulate. But by insisting that Congress may reach any noncommercial act that affects regulation of commercial activity, the Government flatly rejects this Court's holdings in *Lopez* and *Morrison*.

Indeed, it is not hard to come up with plausible "comprehensive scheme" arguments to uphold the statutes struck down in those two cases. Certainly the federal gun laws entail a "comprehensive scheme" for the regulation of firearms, and the Government could reasonably have characterized the Gun Free School Zones Act, 18 U.S.C. § 922(q), as part of that scheme. It might have said, for instance, that the federal gun laws are concerned with the possession of guns by minors, and that schools are a place where distribution of guns to minors is particularly likely to take place. And because it is always difficult to catch people in the act of sale itself, possession laws are a necessary supplement to distribution restrictions.

Likewise, in *Morrison*, the Government might have said that one of the primary achievements of federal regulation has been the opening of job opportunities for women under Title VII of the 1964 Civil Rights Act, 42 U.S.C. § 2000(e), and that the purposes of that and other valid federal statutes are undermined when women are deterred or incapacitated from entering the work force. Violence against women plainly does deter or incapacitate many women from taking advantage of employment opportunities created in part by federal law. Hence, the Government might have said that the Violence Against Women Act, 42 U.S.C. § 139817, was needed as part of a comprehensive scheme to facilitate the equal participation of women in the workforce.

One might respond to this latter argument by accepting a purely formal limitation on the "comprehensive scheme" principle. The VAWA, after all, was not actually enacted in connection with Title VII or other laws designed to ensure workplace equality. But that is hardly much of a limit; the argument suggests that Congress could reenact these laws simply by repackaging them as amendments to other statutes. More important, the formal conception ignores the frequently incremental way that the Congress actually enacts legislation. Different elements of a "comprehensive scheme" are typically enacted at different times under different names; the federal "scheme" to promote gender equality in the workplace, for instance, surely encompasses not only Title VII but also the Equal Pay Act, 29 U.S.C. § 206(d), the Family Medical Leave Act, 29 U.S.C. § 2601 et seq., and possibly other laws. If the "comprehensive scheme" principle is to be contained, this purely formal approach will not do.

This Court's decisions suggest two different limits, one focusing on process and the other on substance. The process principle insists that the necessity be grounded in Congress's actual purposes and judgments. Although Congres may regulate commercial activity for any purpose it likes, *see United States v. Darby*, 312 U.S. 100, 114 (1941), the Court has been more wary of "pretextual" purposes under the Necessary and Proper Clause, *see McCulloch v. Maryland*, 4 Wheat. (17 U.S.) 316, 423 (1819). At the very least, necessity claims should be grounded in the actual purpose motivating Congress's invocation of the commerce power. Moreover, Congress itself should have to make the judgment that reaching noncommercial activity is necessary. The "political safeguards of federalism" are important but limited, and courts have a role in ensuring that those safeguards play their intended role. In *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of*

Engineers, 531 U.S. 159 (2001), for example, this Court held that the decision to regulate at the outer limit of the commerce power must come from *Congress*, not from an administrative agency.

The substantive limit builds on *Lopez*'s definition of the "comprehensive scheme" exception as limited to situations in which the regulation of noncommercial acts is necessary as "an essential part of a larger regulation of economic activity." 514 U.S. at 561. Congress's judgment of necessity should receive some deference, but that deference cannot be absolute unless this Court is prepared to abandon the limits announced in *Lopez* and *Morrison*. *Lopez* framed the "comprehensive scheme" principle in quite restrictive terms, stating that the regulation of noncommercial activity must be "an *essential* part of a larger regulation of economic activity." 514 U.S. at 561 (emphasis added). That wording suggests something stronger than the deferential means/ends standard generally applied under the Necessary and Proper Clause. Indeed, in *McCulloch*, Chief Justice Marshall made much of the absence of any word like "essential" in that clause. 4 Wheat. (17 U.S.) at 418-19. And, as already noted, the Court's move from *interstate* commerce to mere commercial activity already stretches Congress's Necessary and Proper authority.

Determining what must be included in a "comprehensive scheme" of regulation will, of course, entail some factual and policy judgments that are primarily within Congress's competence. At a minimum, however, the courts should insist that those judgments have some reasonable basis in fact. Such a requirement would be consistent with this Court's treatment of the legislative record in *Lopez* and *Morrison*, in which both the majority and dissenting opinions agreed that the role of legislative findings is to assist the Court in determining *for itself* the reasonableness of Congress's judgment of economic effects. *See Lopez*, 514 U.S. at 562-63; *id.* at 616-17 (Breyer, J., dissenting); *Morrison*, 529 U.S. at 614; *id.* at 628 (Souter, J., dissenting).

B. This Court should reject the "comprehensive scheme" argument in this case because it does not reflect Congress's own judgment and because it lacks an adequate foundation in the record.

The Government can meet neither the process nor the substantive standard in this case. On the process side, the linkages drawn between medical and non-medical uses bear only a tenuous relationship to the likely purposes of the CSA. The Government has argued, for example, that medical cannabis may substitute for other painkillers, thereby affecting the market for those drugs. But that effect is relevant only if Congress's purpose in regulating that second market has to do with *prices*; in *Wickard*, for example, Congress was centrally concerned with supporting the price of wheat, and it was therefore important to regulate home-grown wheat production that would trade off with purchases in the commercial market. *See* 317 U.S. at 128-29. There is no evidence in the present case that the United States seeks to support the price of cannabis – or any substitute pain reliever – in the commercial market.

Similarly, the judgment of necessity that would permit regulation of noncommercial activities is far from evident in the text, structure, or legislative history of the statute. The Government's brief suggests various ways in which permitting medical uses *might* undermine drug enforcement efforts in the commercial office, but there is very little evidence that Congress had any of these points in mind when it enacted the Controlled Substance Act. The most plausible account of that Act is that Congress chose to prohibit all marijuana use not because it thought about whether medical uses would undermine regulation of the commercial market, but because it simply believed there were *no* valid medical uses. That is a judgment reasonable people differ on, but it has nothing to do with necessity.

The Court should also review the substance of the necessity determination. This Court has been skeptical of arguments that the

Government must be allowed to restrict activity that it could not otherwise constitutionally reach, simply because such action would facilitate the enforcement of other valid regulations. In this case, for example, the Government has argued that the mere existence of legal medical uses for cannabis would create evidentiary difficulties for recreational-use prosecutions, because prosecutors would be forced to prove that the defendant lacked a medical reason for his use. That argument is remarkably similar to an argument made by the Government, and rejected by this Court, in *Ashcroft v. Free Speech Coalition*, 535 U.S. 234 (2002). In that case, the Government defended a prohibition on "virtual" child pornography on the ground that it would be difficult to prove in court that real child pornography – which the Government has validly banned – was not virtual in its origin. The Court subjected that claim to searching scrutiny and emphatically rejected it. *See id.* at 254-55.[15]

Second, the necessity judgment is a practical one, and it should not be indifferent to the content of *state* law for the same reasons we discussed in Part II. Many of the Government's arguments, however, completely ignore the fact that the State of California has also regulated medical cannabis use here.[16] The government claims that barring Congress from restricting noncommercial medical uses would mean that "persons operating intrastate could function essentially as unregulated and unsupervised drug manufacturers and pharmacies." Pet. Br. 34. This assertion ignores, of course, the fact that the "federal controls Congress put in place under the CSA," *id.*, are not the only regulation in the picture. California itself extensively regulates the medical use at issue here, *see* Resp. Br. 1-2 & n.2, and the competence of state governments to regulate conduct falling outside the scope of Congress's enumerated powers is a basic assumption of our Constitution.

By contrast, the case for federal regulation of noncommercial acts as part of a "comprehensive scheme" will often be stronger where there is no relevant state regulation. The Government argues, for instance, that the mere existence of lawful uses for cannabis will make it more difficult to prove, in any given prosecution, that the use at issue was *un*lawful. That is highly implausible in light of California's scheme, which permits qualified patients who satisfy the requirements for medical use to obtain ID cards demonstrating the lawfulness of their conduct under state law, *see* Resp. Br. 2 n.2; the presence or absence of a lawful medical use thus is not only readily provable in court, but also readily demonstrable to law enforcement officers in the field. But the Government's argument is more powerful as applied to *recreational* users who have neither purchased nor transported their marijuana. Whether or not their possession is "commercial" in nature, the absence of any measures under state law to license and readily identify such purely intrastate uses gives rise to a far stronger argument for inclusion of such conduct within the federal regulatory scheme.

Finally, while reviewing whether the Government's necessity arguments have an adequate foundation is not easy, the Court need not define the precise contours of such review in this case. The matter is here on appeal from the Ninth Circuit's determination that Respondents were entitled to a preliminary injunction. There has

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[15] *Free Speech Coalition* was, of course, a First Amendment case, and we do not argue that the standard of review should be the same here. We do note that conduct falling outside the Commerce Clause is constitutionally protected from *federal* regulation much as expressive conduct is. Indeed, the reason that free speech and other individual rights protections were not included in the original Constitution was that, in the Federalists' view, Congress had not been given *enumerated* power to reach the conduct later protected by express rights. *See* The Federalist No. 84, at 513-15 (Alexander Hamilton) (Clinton Rossiter ed. 1961).

[16] It is unclear what the Government means when it repeatedly says that the CSA is a "closed system" of drug regulation, but the most natural meaning – that Congress has preempted the field of drug regulation – is plainly untrue. No one disputes, for instance, that California is entitled to enforce its own laws *restricting* the use of drugs covered by the CSA.

been no trial in which the Government might develop the factual basis for its judgment that regulating medical cannabis is an "essential part of a larger regulation" of the illegal drug market. It will be easier to develop standards for judicial review of such a record once the Court can see what such a record might look like. In order to decide this appeal, this Court need only decide that some factual showing is necessary and that no such showing has yet been made.

Conclusion

The judgment of the U.S. Court of Appeals for the Ninth Circuit remanding for entry of a preliminary injunction should be affirmed.

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In The Supreme Court of the United States

JOHN D. ASHCROFT, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

ANGEL McCLARY RAICH, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF THE DRUG FREE AMERICA FOUNDATION, INC., THE DRUG FREE SCHOOLS COALITION, SAVE OUR SOCIETY FROM DRUGS, THE INTERNATIONAL SCIENTIFIC AND MEDICAL FORUM ON DRUG ABUSE, THE INSTITUTE ON GLOBAL DRUG POLICY, AND STUDENTS TAKING ACTION NOT DRUGS, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate cultivation and possession of marijuana for the purported personal "medicinal" use or to the distribution of marijuana without charge for such use?

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INTEREST OF *AMICI*

Amici Curiae are parents, drug-prevention organizations, distinguished medical and scientific experts, policy makers, non-profit corporations, business owners and others who are concerned with preventing drug abuse, and who all share a common concern that smoked or crude marijuana is disingenuously referred to as medicine. The international makeup of Amici reflects the international concern that illicit drug use is undercutting traditional values and threatening the very existence of stable families, communities, and government institutions throughout the world. Amici collectively support families, communities, and nations that are free of illicit drug use, drug abuse, drug addiction, and drug-related deaths through advocacy and solid medical and scientific research and oppose the de jure and de facto legalization of marijuana and all other current illicit drugs. Smoked or "crude" marijuana is a dangerous Schedule I drug, notwithstanding creative attempts by those who seek its legalization to label its use as "compassionate" in medical settings. Medical marijuana initiatives now enacted in ten states and the District of Columbia undermine national drug-enforcement priorities and our well-designed federal system of approval of new drugs. While future use of the state ballot initiative process as a tool to replace the legislative process must be dealt with by state legislatures, ultimately the federal government and courts must address this important issue to ensure a consistently applied and clearly understood national drug policy, as well as to preserve the Food and Drug Administration's medical and scientific new drug approval process that protects Americans from unsafe, ineffective drugs. This brief is submitted to present to the Court current research which confirms

that the drug marijuana continues to have no currently accepted medical use.

The complete list of *amici* is listed in the Appendix, as App. 8.

SUMMARY OF ARGUMENT

There is still no proven medical value to the use of crude marijuana. This remains the unequivocal position of the Food and Drug Administration, which is charged by Congress with making this determination. The Appellate Court's decision (finding a strong likelihood of success on the merits of appellants' commerce clause claim) rests on its identification of a *separate class* of activities regarding the use of crude marijuana for personal medical purposes, such that this class of activities exists outside the scope of the class of drug-related activities reached by the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* Absent a legitimate and currently accepted medical use for crude marijuana, the Appellate Court's reasoning must fail, as it would therefore have no basis for establishing this separate class of drug use which is independent of the Controlled Substances Act. As demonstrated herein, both federal law and the weight of medical research continue to find crude marijuana use to be dangerous and without legitimate medical application. Therefore the Appellate Court's necessary foundational premise (i.e., the existence of private, non-commercial *medical* use of marijuana) is invalid, and the "separate class of activities" envisioned by the Appellate Court cannot exist. Simply put, if there is no currently accepted medical use for marijuana, then the activity at issue must, by the appellate court's own analysis,

fall within the jurisdictional scope of the Controlled Substances Act, pursuant to its authority under the Commerce Clause, and therefore there is no possibility of success on the merits of the appellant's commerce clause claim, and the decision below must be reversed.

ARGUMENT

I. BECAUSE CRUDE MARIJUANA[1] HAS NO CURRENTLY ACCEPTED MEDICAL USE, ITS PURPORTED MEDICAL USE CANNOT CONSTITUTE A CLASS OF ACTIVITIES SEPARATE FROM THE ACTIVITIES REGULATED BY THE CONTROLLED SUBSTANCES ACT ("CSA"), AND THE CSA, PURSUANT TO THE COMMERCE CLAUSE POWERS, HAS JURISDICTION OVER ANY AND ALL MARIJUANA USE

In *Raich v. Ashcroft*, 352 F.3d 1222 (9th Cir. 2003), the Appellate Court reversed the District Court's decision denying the appellants' motion for a preliminary injunction halting enforcement of the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA"). The District

[1] Throughout this brief we use the term "crude marijuana" to describe the illicit Schedule I drug that people abuse. The drug is derived from the leaves and flowering tops of the Cannabis plant and is consumed in a variety of ways. The dried plant material is most often rolled in paper and smoked as a cigarette, called a "joint." It is often placed in smoking devices called "bongs," smoked in pipes, or smoked in "blunts," which are cigars from which the tobacco has been removed and replaced with marijuana plant material. Sometimes it is baked in cookies or brownies and eaten, or brewed in tea and drunk. Other methods for consuming the drug are constantly being developed by the drug culture, including versions that allegedly aerosolize crude marijuana to remove its "tars."

Court had found that the Commerce Clause [U.S. Const. art. I, sec 8, cl.3] supported the application of the CSA. The Appellate Court disagreed. Employing *United States v. McCoy*, 323 F.3d 1114 (9th Cir. 2003) as precedent, the Appellate Court found that the appellants' conduct may represent a "substantial portion" of the conduct covered by the relevant statute, and therefore can be examined as a "separate class of activity," which, if purely intrastate and having no effect on interstate commerce, can be outside the scope of the statute, and beyond the jurisdictional authority provided by the Commerce Clause. *Raich*, at 1228-1234. The court identified this separate class of activities as "the intrastate, non-commercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician and in accordance with state law." *Id.*, at 1229. The state law to which the court refers is California's Compassionate Use Act, Cal. Health & Safety Code 11362.5. Using the foregoing analysis, the court found "a strong likelihood of success" to the appellants' claim for injunctive relief.

The obvious lynchpin in this "separate class" carved out by the court is the purported "medical use" of the marijuana. The Appellate Court itself conceded that, "Indeed, we have upheld the CSA in the face of past Commerce Clause challenges . . . [b]ut none of the cases in which the Ninth Circuit has upheld the CSA on Commerce Clause grounds involved the use, possession, or cultivation of marijuana for *medical purposes*." *Id.*, at 1227 (emphasis added). As Justice Beam pointed out in his dissent: "Except for why the marijuana at issue in this case is consumed, i.e., for medicinal rather that nutritional purposes, plaintiffs' conduct is entirely indistinguishable from that of Mr. Filburn's." *Id.*, at 1238. Justice Beam was referring to

the defendant in *Wickard v. Filburn*, 317 U.S. 111, 63 S.Ct. 82, 87 L.Ed. 122 (1942), in which, under the Commerce Clause, the Agriculture Adjustment Act reached Filburn's wheat growing activities, even that part of the crop grown for family food consumed in the home on the Filburn farm.

While the majority disagreed with Justice Beam's assertion that "[i]t is simply impossible to distinguish the relevant conduct surrounding the cultivation and use of the marijuana crop at issue in this case from the cultivation and use of the wheat crop that affected interstate commerce in *Wickard v. Filburn*" (*Raich*, at 1235), what is beyond dispute is that the majority's decision hangs solely on its (largely unexamined) premise that there exists a legitimate medical use for the ingestion of crude, or homegrown, marijuana. The Court's only bases for this premise appear to be the various state medical marijuana laws which permit the use of crude marijuana pursuant to a physician's recommendation. While these state laws may create an inference of legitimacy to the concept of "medical marijuana," they must be viewed in the context of, and weighed against, the body of unambiguous and preemptive federal law with which it plainly conflicts, and which has consistently held the position that there is no currently accepted medical use for crude marijuana.

There is a strong governmental interest in prohibiting the distribution of crude marijuana as medicine (See: Sections II and III, below). The federal government has expressly taken on the job of protecting our citizens from unsafe, ineffective substances sold as "medicines," and from drug abuse, drug addiction, and the abusive and criminal behaviors that marijuana and other illicit drugs often generate. Before any drug can be classified as "medicine," the drug must first be approved by the Food and

Drug Administration (the "FDA"). The federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 351-360, gives the federal government, through the FDA, *sole responsibility* for determining that drugs are safe and effective, a requirement all medicines must meet before they may be distributed to the public. The FDA has not approved marijuana as safe or effective, so the drug may not legally be prescribed and sold as a medicine.

Not only has the FDA failed to approve marijuana, but has classified marijuana as a Schedule I controlled substance under the Controlled Substances Act. Schedule I drugs have "1) a high potential for abuse, 2) no currently accepted treatment in the United States, and 3) a lack of accepted safety for use of the drug ... under medical supervision." 21 U.S.C. § 812(b)(f).

In *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994), the United States District Court for the District of Columbia accepted the Drug Enforcement Administration's new five-part test for determining whether a drug is in "currently accepted medical use." *Id.* at 1135. The test requires that:

(1) The drug's chemistry must be known and reproducible;

(2) there must be adequate safety studies;

(3) there must be adequate and well-controlled studies proving efficacy;

(4) the drug must be accepted by qualified experts; and

(5) the scientific evidence must be widely available.

Applying these criteria to a petition to reschedule crude marijuana, the court found that the drug had no currently accepted medical use and, therefore, must remain a Schedule I substance. It should be noted that although the FDA has not approved crude marijuana as safe and effective, the FDA *has* approved medications to treat all of the diseases, symptoms, and ailments identified in California's Compassionate Use Act, and therefore, safe and effective legal alternatives to crude marijuana exist (See: Section II (b), below).

More recently, The FDA issued the following Statement, released in response to a congressional debate on the issue of medical marijuana use:

> The Food and Drug Administration (FDA) has concerns about any legislation that would prevent the Department of Justice or the Drug Enforcement Agency (DEA) from enforcing the Controlled Substances Act (CSA) with respect to marijuana either generally or in specified States. Marijuana is a Schedule I drug under the CSA. Schedule I substances are defined as having a high potential for abuse and no accepted medical use in the U.S. In 2001, the Department of Health and Human Services (HHS) completed an extensive analysis in response to a request to reschedule marijuana to a less restrictive schedule. After looking at all the relevant data on marijuana, HHS concluded that marijuana should continue to be controlled under Schedule I. DEA is the Federal agency with primary jurisdiction regarding enforcement actions relating to the sale or distribution of marijuana. FDA will continue to cooperate with DEA in these actions.

Several states have passed referenda making marijuana available for a variety of medical conditions, but these laws are in conflict with the CSA and often with the Federal Food, Drug, and Cosmetic (FD&C) Act. FDA's position continues to be that these ballot measures send the wrong message to the public – too many of whom do not recognize the dangers of marijuana – and that these measures are inconsistent with our efforts to ensure that approved medications have undergone rigorous scientific scrutiny and FDA's approval process.

FDA is the sole Federal agency that approves drug products as safe and effective for particular indications, and efforts that seek to bypass the FDA drug approval process would not serve the interests of public health. FDA has not approved marijuana for any indication. Only the disciplined, systematic, scientific conduct of clinical trials can establish whether there is any medicinal value to marijuana, smoked or otherwise.

> We reiterate that any legislation that would prevent the Department of Justice or the DEA from enforcing the CSA with respect to marijuana either generally or in specified States would not serve the interests of public health.[2]

In *United States v. Oakland Cannabis Buyers' Cooperative*, 523 U.S. 483 (2001), this Court held that "a medical necessity exception for marijuana is at odds with the terms of the Controlled Substances Act" because "its provisions leave no doubt that the defense is unavailable."

[2] FDA Statement, July 7, 2004. Released for House debate on issue of medical marijuana use; Patrick Ronan, Ass't Commissioner for Legislation, FDA.

Id., at 491. The Court added that "[t]he very point of our holding is that there is no medical necessity exception to the prohibitions at issue, even when the patient is seriously ill and lacks alternative avenues for relief." *Id.*, at 494 n.7. If "medical necessity" is insufficient to escape the scope of the CSA, then certainly mere "medical use" cannot suffice to comprise a separate distinct class of activity beyond the scope of the Controlled Substances Act.

Indeed, according to federal law, "medical marijuana" is a non sequitur. It cannot be re-animated, phoenix-like, at the state level, simply to create an otherwise unavailable refuge from the scope of the Commerce Clause.

II. ADVOCATES HAVE TRIED TO LEGALIZE MARIJUANA IN ONE FORM OR ANOTHER FOR THREE DECADES, AND THE "MEDICAL MARIJUANA" CONCEPT IS A TROJAN HORSE TACTIC TOWARDS THE GOAL OF LEGALIZATION

Drug-legalization advocates over the last three decades have employed a number of political and legal strategies to legalize marijuana. Between 1972 and 1978, the National Organization for the Reform of Marijuana Laws (NORML) successfully lobbied eleven state legislatures to "decriminalize" the drug, reducing penalties for possession in most cases to that of a traffic ticket. Also in 1972, NORML began the first of several unsuccessful attempts to petition the Drug Enforcement Administration (DEA) to reschedule marijuana from Schedule I to Schedule II on the grounds that crude marijuana had putative use in medicine. These attempts failed. See, *National Org. for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 654 (D.C. Cir. 1974); *National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin.*, 559 F.2d 735 (D.C. Cir.

1977); *National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin. & Dept. of Health, Education & Welfare*, No. 79-1660 1980 U.S. App. LEXIS 13099 (D.C. Cir. Oct. 16, 1980); and *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).

NORML and others led a second lobbying campaign aimed at states in the 1980s, this time to legalize crude marijuana as medicine. Some 35 states passed such laws. However, these laws were written by state legislative counsels, and so were appropriately drafted within the framework of federal law, establishing statewide research programs as directed by the applicable FDA guidelines. As a result, the advocates failed to get what they wanted – freely available marijuana.

In the early 1990s, NORML, the Drug Policy Foundation (DPF), and The Lindesmith Center (TLC) renewed the effort to legalize crude marijuana as medicine, this time using the state ballot initiative process, a process that allowed advocates to circumvent state legislative counsels and write their own laws. NORML, DPF, and TLC persuaded their most generous funders to create political organizations – Californians for Medical Rights and Arizonans for Drug Policy Reform – and to finance the first two medical marijuana initiatives in California and Arizona in 1996 and all subsequent initiatives that have passed since then. After the first two initiatives, Californians for Medical Rights became Americans for Medical Rights (AMR), which led successful medical marijuana initiative campaigns in 1998 in Alaska, Colorado, Nevada, Oregon, and Washington and in 1999 in Maine (See: Table 1). Similar initiatives were recently passed in Maryland and Vermont. Different sponsors succeeded in passing a

medical marijuana initiative in the District of Columbia 1998, with assistance from AMR.

California's Compassionate Use Act [Cal. Health & Safety Code 11362.5] legalizes crude marijuana for "the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, *or any other illness for which marijuana provides relief"* (emphasis added). After the proposition passed, its author told the press that *anyone* who uses marijuana is "self-medicating" and that therefore *all* marijuana use is for medical purposes. "The Return of Pot", Hanna Rosin, *The New Republic*, February 17, 1997.

A. The Fact That One Chemical In Marijuana Is An FDA-Approved Medicine Does Not Make Crude Marijuana An Approved Medicine.

Crude marijuana is derived from the leaves and flowering tops of the Cannabis plant. It contains some 400 chemicals, most of which have not been studied by scientists. Some 60 of these chemicals, called cannabinoids, are unique to the Cannabis plant. One cannabinoid, Delta_9_tetrahydrocannabinol (THC), was synthesized, tested, and approved by FDA in 1985 for treating nausea in cancer patients and wasting in AIDS patients. The drug's generic name is dronabinol and its trade name is Marinol^{R}. It is produced by Unimed Pharmaceuticals.

According to John A. Benson, Jr. M.D. of the Institute of Medicine, research on other cannabinoids is underway and some of these chemicals may one day prove to be useful medicines. However, he states:

> While we see a future in the development of chemically defined cannabinoid drugs, we see little future in smoked marijuana as a medicine.[3]

The fact that crude marijuana contains a chemical that has been synthesized, tested, and approved for medical use does not make marijuana itself a safe or effective medicine. Modern pharmaceutical science would require all the 400 or more chemicals in marijuana to pass the safety and efficacy tests in research, and this has not happened. Any consideration of this issue must take into account the substantial toxicity and morbidity associated with marijuana use. Because of the impurity of crude marijuana and its known toxic effects, it does not represent a useful medical alternative to currently available medications.

The current efforts to gain legal status of marijuana through ballot initiatives seriously threaten the Food and Drug Administration statutorily authorized process of proving safety and efficacy. The ballot initiative-led laws create an atmosphere of medicine by popular vote, rather than the rigorous scientific and medical process that all medicines must undergo. Before the development of modern pharmaceutical science, the field of medicine was fraught with potions and herbal remedies. Many of those were absolutely useless, or conversely were harmful to unsuspecting subjects. Thus evolved our current Food and Drug Administration and drug scheduling processes, which Congress has authorized in order to create a uniform and reliable system of drug approval and regulation.

[3] John A. Benson, Jr., Co-Principal Investigator, in releasing *Marijuana and Medicine: Assessing the Science Base*, Institute of Medicine, National Academy of Sciences, 1999.

This system is being intentionally undermined by the legalization proponents through use of medical marijuana initiatives.

B. Suitable And Superior Medicines Are Currently Available For Treatment Of All Symptoms Alleged To Be Treatable By Crude Marijuana.

Having extensively reviewed available therapies for chemotherapy-associated nausea, glaucoma, multiple sclerosis, and appetite stimulation,[4] Drs. Voth and Schwartz have determined that no compelling need exists to make crude marijuana available as a medicine for physicians to prescribe. They concluded that the most appropriate direction for THC research is to research specific cannabinoids or synthetic analogs rather than pursuing the smoking of marijuana. The conclusions of Drs. Voth and Schwartz were echoed a year later by the National Academy of Science's Institute of Medicine (hereinafter "IOM Report") in an assessment of scientific marijuana and cannabinoid research (see below).[5]

Available research on the utility of THC has demonstrated some effectiveness of the purified form of the drug in treating nausea associated with cancer chemotherapy.

[4] Voth EA, Schwartz RH. Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana. *Annals of Internal Medicine* 1997;126:791-798.

[5] *Marijuana and Medicine: Assessing the Science Base.* Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health. Institute of Medicine, National Academy of Sciences. National Academy Press, Washington D.C., 1999.

Examples of such research include Sallan, et al.[6] who dealt only with pure THC in the treatment of chemotherapy-associated nausea, not smoked marijuana. Chang[7] tested THC and then followed treatment failures with marijuana, thus conclusions regarding effectiveness cannot be readily attributed to either THC or crude marijuana. Levitt[8] and coworkers actually determined that purified THC was more effective than smoked marijuana. Vinciguerra[9] found that smoked marijuana controlled nausea in patients who had failed other conventional forms of antiemetic therapy. Responders tended to have had prior marijuana experience. This study was uncontrolled and patients self-evaluated results. Smokers were required to inhale deeply, hold the smoke for ten seconds, and then smoke four cigarettes completely each day of chemotherapy. Twenty-five percent refused to smoke the marijuana. Over 20% of the subjects dropped out of the smoking group prior to the end of the study and 22% of the remaining subjects reported no benefit from smoking marijuana. Dosing was also variable because of the fact that the dose was rounded to the nearest one-fourth marijuana cigarette, and no THC levels were checked for consistency of dose response.

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[6] Sallan S S, et al. Antiemetics effects of delta-9-tetrahydrocannabinol in patients receiving cancer chemotherapy. *NEJM*. 1975;293:795-797.

[7] Chang et al. Delta-9-tetrahydrocannabinol as an antiemetic in cancer patients receiving high-dose methotrexate. *Annals of Internal Medicine*. 1979;91:819-924.

[8] Levitt et al. Randomized double blind comparison of delta-9-tetrahydrocannibinol and marijuana as chemotherapy antiemetics. *Proceedings of the Annual Meeting of the American Society of Clinical Oncology*. 1984:91

[9] Vinciguerra V, Moore T, Brennan E: Inhalation marijuana as an antiemetic for cancer chemotherapy. *N.Y. State J Med* 1988; 88:525-527.

Legalization advocates would have the public and policy makers incorrectly believe that crude marijuana is the only treatment alternative for masses of cancer sufferers who are going untreated for the nausea associated with chemotherapy, and for all those who suffer from glaucoma, multiple sclerosis, and other ailments. Numerous effective medications are, however, currently available for conditions such as nausea (See: Appendix, Table 2).

In fact, the IOM report found that neither smoked marijuana nor cannabinoids are as effective as current medicines that stop nausea and vomiting in cancer chemotherapy patients. However, the scientists speculated that cannabinoids might be effective in those few patients who respond poorly to current antiemetic (anti-nausea) drugs or more effective in combination with current antiemetics. It recommended that research should be pursued for patients who do not respond completely to current antiemetics and that a safe (non-smoking) delivery system for cannabinoids should be developed.

The negative side effect profile for marijuana, even oral dronabinol (Marinol^{R}), far exceeds most of the other effective agents available. *If* there exist treatment failures of available medications in these patients, the use of marijuana would, at minimum, demonstrate unpleasant side effects. In the studies performed to examine THC for chemotherapy-associated nausea, elderly patients could not tolerate the drug. Chronic, daily doses of the drug would be necessary to treat many of the proposed medical conditions. This would unnecessarily expose the patients to the toxic effects.

Mattes[10] compared oral and rectal suppository preparations of THC with smoked marijuana. All study subjects were experienced marijuana users thus accounting for a relatively high drug acceptance. Smoked marijuana was no more effective than suppository THC in stimulating appetite as measured by caloric energy intake. Rectal suppositories and oral THC were dosed at 2.5 mg twice daily. Marijuana subjects were required to inhale for 3 seconds, hold the smoke deeply in their lungs for 12 seconds, and then continue the process until the cigarette was smoked to a stub. The plasma THC levels peaked more quickly with the inhaled THC, but also fell more quickly, whereas the suppository THC maintained a more sustained level.

To examine the potential medical efficacy of marijuana as it relates to several disease states, a comprehensive review of the potential medicinal applications of marijuana was recently undertaken at the request of the Assistant Secretary of Health, Dr. Phillip Lee. Opinions were requested from investigators at the National Institute on Allergy and Infectious Diseases, who commented on the AIDS wasting syndrome; the National Cancer Institute who commented on the use of marijuana as an antiemetic in cancer chemotherapy; the National Eye Institute who commented on marijuana's use in glaucoma; and the National Institute for Neurological Disorders and Stroke who commented on marijuana's role as an antispasticity drug in multiple sclerosis. The summary opinion stated:

[10] Mattes RD, Engelman K, Shaw LM, Elsohly MA. Cannabinoids and appetite stimulation. *Pharmacologic Pharmacology, Biochemistry, and Behavior,* 1994;49:187-195.

> This evaluation indicates that sound scientific studies supporting these claims are lacking despite anecdotal claims that smoked marijuana is beneficial. Scientists at the National Institutes of Health indicate that after carefully examining the existing preclinical and human data, there is no evidence to suggest that smoked marijuana might be superior to currently available therapies for glaucoma, weight loss associated with AIDS, nausea and vomiting associated with cancer chemotherapy, muscle spasticity associated with multiple sclerosis, or intractable pain.[11]

The National Institutes of Health reconsidered this issue in 1997[12] and has called for further research into alternate delivery systems for pure THC as well as research into the comparative efficacy of marijuana with newer available medicines which have added heightened efficacy to medication regimes. The summary also called into attention concern over pulmonary, neuro-, and immuno-toxicity of cannabis.

In 1997 the White House Office of National Drug Control Policy commissioned the National Academy of Sciences Institute of Medicine (IOM) to undertake an evaluation of the utility of marijuana and other cannabinoids[13] for medicinal applications. The study concluded

[11] Lee PR, Letter to Congressman Dan Hamburg, United States Public Health Service, July 13, 1994

[12] Workshop on the Medical Utility of Marijuana. Report to the Director, National Institutes of Health. http://www.nih.gov/news/pr/aug97/nih-08.htm

[13] Marijuana and Medicine: Assessing the Science Base Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health, Institute of Medicine. National Academy Press, Washington, D.C. 1999. Internet address www.nap.edu

that the challenge for future research will be to find cannabinoids which enhance therapeutic benefits while minimizing side effects such as intoxication and dysphoria. Delivery systems such as nasal sprays, metered dose inhalers, transdermal patches, and suppositories could be useful delivery systems for isolated or synthetic cannabinoids (See: Appendix, Table 3). The future for medicinal applications of cannabinoids and whether cannabinoids are equal or superior to existing medicines remains to be determined, but the IOM evaluation is particularly clear on the smoking of marijuana:

> If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of a rapid-onset, non-smoked cannabinoid delivery system.[14]

The following excerpts from the IOM report are instructive:

> The goal for drugs that treat nausea and vomiting produced by cancer chemotherapy is complete control (stop vomiting completely) or major control (two or fewer episodes of vomiting). . . .[15] A controlled double-blind study compared THC with a standard antiemetic drug, metoclopramide, in cancer patients who received cisplatin,

[14] IOM Report, p. 20.

[15] Ibid., p. 4.11.

> the chemotherapeutic drug that causes vomiting in more than 99 percent of patients. . . .[16]

Results	Complete Control	Major Control
Metoclopramide	47 percent	73 percent
THC	13 percent	27 percent

> (Other study) results suggest that THC reduces chemotherapy-induced emesis. These studies also indicate that the degree of efficacy is not high. . . .[17] As with the THC trials, nabilone and levonantradol (two synthetic analogues of THC) reduced emesis, but not as well as other available agents. . . .[18] A double-blind, cross-over, placebo controlled study compared THC pills to smoked marijuana in 20 cancer patients receiving a variety of chemotherapeutic drugs. Only 25 percent of patients achieved complete control of vomiting. . . .[19]

Preferred THC Pills	35 percent
Preferred Marijuana	20 percent
No Preference	45 percent

> Although many marijuana users have claimed that smoked marijuana is a more effective antiemetic than oral THC, no controlled studies have yet been published that analyze this in sufficient detail to estimate the extent to which that is the case. . . .[20] *Major progress, generally not well-known to the public, in controlling chemotherapy-induced acute nausea and vomiting has*

[16] Ibid., p. 4.11-4.12.

[17] Ibid., p. 4.12.

[18] Ibid., p. 4.13.

[19] Ibid., p. 4.13.

[20] Ibid., p. 4.14.

been made since the 1970s (emphasis added). Patients receiving the most difficult to control emetic agents now have no more than a 20-30 percent likelihood of experiencing acute emesis, whereas in the 1970s the likelihood was nearly 100 percent despite (then standard) antiemetics. . . . [21] Cannabinoids are not as effective as several other classes of agents . . . . As with cannabinoids, efficacy was apparent with smoked marijuana, but the degree of efficacy was no better than that seen with available antiemetic agents now considered to be marginally satisfactory. It is theoretically possible . . . that added to more effective regimens, THC might enhance control of emesis. . . . The critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but rather whether there is a group of patients who might obtain added or better relief from marijuana or cannabinoid drugs. . . .[22] Most chemotherapy patients are unlikely to want to use marijuana or THC as an antiemetic. In 1998, there were more effective antiemetic agents available than were available earlier. By comparison, cannabinoids are only modest antiemetics . . . .However . . . cannabinoids might be effective in people who respond poorly to currently used antiemetic drugs, or cannabinoids might be more effective in combination with the new drugs than either are alone. . . .Therefore research should be pursued for patients whose nausea and vomiting is not completely controlled by standard antiemetics. . . . Antiemetic pills are given to cancer patients before chemotherapy begins and then

[21] Ibid., p. 4.15.

[22] Ibid., p. 4.16.

afterwards. In those patients who nonetheless experience nausea and vomiting after chemotherapy, "an inhalation (but preferably not smoking) cannabinoid drug delivery system would be advantageous for treating chemotherapy-induced nausea."[23]

C. Crude Marijuana Use Entails Numerous Significant And Proven Negative Effects.

Marijuana adversely impacts concentration, motor coordination, and memory,[24] factors that must be considered in any discussion of providing this drug to patients suffering chronic diseases. The ability to perform complex tasks, such as flying,[25] is impaired even 24 hours after the acute intoxication phase. The association of marijuana use with trauma and intoxicated motor vehicle operation is also well established.[26] This is of central importance in an ambulatory environment where patients may smoke marijuana and then drive automobiles. Recent evaluations[27] of the effect of marijuana on driving determined

[23] Ibid., p. 4.17.

[24] Murray J B. Marijuana's effects on human cognitive functions, psychomotor functions, and personality. *Journal of General Psychology.* 1986;113:23-55.

[25] Yesavage J A, Leirer V O, Denari M, and Hollister L E. Carryover effects of marijuana intoxication on aircraft pilot performance; a preliminary report. *Am. J. Psychiatry.* 1985;142:1325-1329.

[26] Gerostamoulos J., and Drummer O H. Incidence of psychoactive cannabinoids in drivers killed in motor vehicle accidents. *Journal of Forensic Sciences.* 1993;38:649-656.

[27] National Highway Traffic Safety Administration. Marijuana and Alcohol Severely Impede Driving Performance. *Annals of Emergency Medicine*2000:35;398-399. NHTSA study– National Highway Traffic Safety Administration. Marijuana Alcohol and Actual Driving Performance. DOT HS 808.939

that the combination of blood alcohol concentrations (BAC) of 0.07 and marijuana 100ug/kg gave effects similar to a BAC of 0.09. Blood alcohol concentrations of 0.07 and marijuana levels of 200ug/kg demonstrated effects similar to a BAC of 0.14 when measuring reaction time, on-road performance, and vehicle following. The study concluded, "Under marijuana's influence, drivers have reduced capacity to avoid collisions if confronted with the sudden need for evasive action." A second related study found that a BAC of .05 combined with moderate marijuana produced a significant drop in the visual search frequency.

Positron scanning[28] of subjects' mean use of marijuana 17 times per week for the last 2 years found lower blood flow in a large region of the posterior cerebellum. Not only does this have implications on motor coordination and function, but also cognition, timing, processing sensory information, and attention.

Despite arguments of the legalization advocates to the contrary, marijuana is a dependence-producing drug. Strangely, in the course of the rescheduling hearings, petitioners admitted that "marijuana has a high potential for abuse and that abuse of the marijuana plant may lead to severe psychological or physical dependence." These are points which they now deny. However, this dependence and associated "addictive" behaviors have been well

[28] Block RI, O'Leary DS, Hichwa RD, Augustinack JC, Boles-Ponto LL, Ghoneim M M, Arndt S, Ehrhardt JC, Hurtig RH, Watkins GL, Hall JA, Nathan PE, Andreasen NC. Cerebellar hypoactivity in frequent marijuana users. *NeuroReport* 2000;4:749-753

described in the marijuana literature.[29] [30] [31] Marijuana dependence consists of both a physical dependence (tolerance and subsequent withdrawal) and a psychological dependence. Withdrawal from marijuana has been demonstrated in both animals[32] and humans.[33]

While the dependence producing properties of marijuana are probably a minimal issue for chemotherapy-associated nausea when medication is required sporadically, it is a major issue for the chronic daily use necessary for glaucoma, AIDS wasting syndrome, and other alleged chronic applications.

The respiratory difficulties associated with marijuana use preclude the inhaled route of administration as a medicine. Smoking marijuana is associated with higher concentrations of tar, carbon monoxide, and carcinogens than are found in cigarette smoking.[34] Marijuana adversely impairs some aspects of lung function and causes abnormalities in the respiratory cell lines from large

[29] Compton D R, Dewey W L, and Martin B R. Cannabis dependence and tolerance production. *Advances in Alcohol and Substance Abuse.* 1990;9:129-147.

[30] Miller N S, and Gold M S. The diagnosis of marijuana (cannabis) dependence. *Journal of Substance Abuse Treatment.* 1989;6:183-192.

[31] Schwartz R H. Marijuana: an overview. *Pediatric clinics of North America.* 1987;34:305-317

[32] Martin BR. The THC receptor and its antagonists. In: Nahas GG, Burks TF, eds. Drug Abuse in the Decade of the Brain. Amsterdam: IOS press;1997:139-144.

[33] Duffy A, Milin R, Case Study: Withdrawal Syndrome in Adolescent Chronic Cannabis Users. *J. Am. Acad Child Adolesc Psychiatry.* 1996;35:1618-21.

[34] Wu T C, et al. Pulmonary hazards of smoking marijuana as compared with tobacco. *NEJM.* 1988;318:347-351.

airways to the alveoli.[35] [36] Marijuana smoke causes inflammatory changes in the airways of young people that are similar to the effects of tobacco.[37] In addition to these cellular abnormalities and consequences, contaminants of marijuana smoke are known to include various pathogenic bacteria and fungi.[38] Those at particular risk for the development of disease and infection when these substances are inhaled are those users with impaired immunity.

One of the earliest findings in marijuana research was the effect on various immune functions, which is now evidenced by an inability to fight herpes infections and the discovery of a blunted response to therapy for genital warts during cannabis consumption.[39] Abnormal immune function is, of course, the cornerstone of problems associated with AIDS. The use of chronic THC in smoked form for AIDS wasting not only exposes the patient to unnecessary pathogens, but also risks further immunosuppression. Evaluation of the effect of THC on NK-*k*B has suggested a possible effect on the HIV genome. A hallmark

[35] Tashkin D P, Shapiro B J, Lee Y E, and Harper C E. Subacute effects of heavy marijuana smoking on pulmonary function in healthy men. *NEJM*. 1976;294:125-129.

[36] Barbers R G, et al. Differential examination of bronchoalveolar lavage cells in tobacco cigarette and marijuana smokers. *Am Rev Respir Dis*1987;135:1271

[37] Roth MD, Arora A, Barsky SH, Kleerup EC, Simmons M, Tashkin DP. Airway inflammation in young marijuana and tobacco smokers. *Am J. Respir Crit Care Med* 1998;157:928-937

[38] Fleisher M, Winawer S J, and Zauber A G. Aspergillosis and marijuana. *Annals of Internal Medicine.* 1991;115:578-579.

[39] Gross G, Roussaki A, Ikenberg, Drees N. Genital warts do not respond to systemic recombinant interferon alfa-2 treatment during cannabis consumption. *Dermatologica* 1991; 183:203-207

of the treatment for AIDS is *avoidance* of drug use, not extension or perpetuation of it. It should be clear that marijuana exposes the user to substantial health risks. In chronic use, or use in populations at high risk for infection and immune suppression, the risks are unacceptable.

Amici assert that in the interest of protecting seriously and terminally ill patients from unsafe and ineffective drugs, the safety and efficacy process of the FDA cannot be bypassed. The FDA has thoroughly examined the possible use and/or re-classification of crude marijuana, and it has correctly determined that crude marijuana is an impure and toxic substance that has no place in the medical armamentarium. Furthermore, by means of its appropriate regulatory processes, the FDA remains available to petitioning for reclassification, should sufficient evidence for such change of classification arise. To date, it has not.

Recently, the medical excuse marijuana movement has been compared to a Pandora's Box which threatens to jeopardize public safety and consumer protection if opened.[40] Coupled with the medical risk to patients, serious regulatory questions arise that have not been adequately dealt with by ballot initiatives. Those who propose medical uses, or who conduct research on the use of marijuana, have an ethical responsibility not to expose their subjects to unnecessary risks. Under current guidelines, crude marijuana is not a medicine, and allowing it as such would be a step backward to the times of potions and herbal remedies.

[40] Voth, EA, *A Peek Into Pandora's Box: The Medical Excuse Marijuana Controversy.* J. Addict. Diseases 2003; 22:27-46

III. THE PUBLIC'S DIMINISHED PERCEPTION OF HARM REGARDING THE USE OF MARIJUANA INCREASES ITS ILLICIT USE

Amici note the profound correlation in benchmark surveys of drug use, which show that the more people who believe a drug is harmful, the fewer people use that drug. Equally profound are the surveys' findings that the reverse is also true: the fewer people who believe a drug is harmful, the more people use that drug. These surveys show that perception of harm with respect to marijuana has been dropping off annually since the renewal of the drive to legalize marijuana as medicine, which began in the early 1990s when legalization advocates first gained a significant increase in funding and began planning the state ballot initiative drive to legalize crude marijuana as medicine. The surveys are the Monitoring the Future Survey, which has tracked drug use among American high school students annually since 1975[41] and the National Household Survey on Drug Abuse, which has tracked drug use among Americans ages 12 and older annually or less frequently since 1972.[42]

The 1999 National Household Survey on Drug Abuse, released in October 2000, was conducted for SAMHSA (the Substance Abuse and Mental Health Services Administration, Department of Health and Human Services) by North

[41] *Monitoring the Future,* National Institutes of Health, National Institute on Drug Abuse, available on the Internet at <www.monitoringthefuture.org>.

[42] *Summary of Findings from the 1999 National Household Survey on Drug Abuse*, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Rockville MD, 2000, pp 64-65, 74-75.

Carolina's Research Triangle Institute.[43] For the first time in the history of this survey, the population sample was vastly increased (from an average of 15,000 to 75,000) in order to provide data about individual states, as well as about the nation as a whole. The state data for the 1999 survey reveals that those states which have passed medical marijuana laws have among the highest levels of past-month marijuana use, of past-month other drug use, of drug addiction, and of drug and alcohol addiction (See: Appendix, Table 4):

> **Drug Addiction** – Alaska and Nevada had the highest rates of drug addiction in the nation, California and Oregon have the 4th highest rates, the District of Columbia has the 5th highest rate, Washington has the 6th highest rate, Arizona and Colorado have the 7th highest rates, and Maine has the 12th highest rate.[44]
>
> **Drug Use** – Alaska has the highest rate of past-month drug use in the nation, Nevada has the 3rd highest rate, Colorado has the 4th highest rate, Washington has the 8th highest rate, California has the 9th highest rate, Oregon has the 11th highest rate, the District of Columbia has the 12th highest rate, and Arizona and Maine have the 15th highest rate.[45]

In 2003 SAMHSA released a follow-up survey, the 2002 National Survey on Drug Use and Health. The results confirm the 1999 findings, and demonstrate a consistent clustering of drug-use issues in states which

[43] Ibid.

[44] Ibid.

[45] Ibid.

have adopted medical marijuana ballot-measures (See: Appendix, Table 5).

> **Drug Addiction and Abuse** – *All* of the medical marijuana ballot-initiative states are now clustered at or near the top of the list in terms of drug addiction and abuse. California and Nevada have the highest rates in the nation. These medical marijuana ballot-initiative states occupy three of the top four slots, and six of the top ten slots. The nine medical marijuana ballot-initiative states now occupy nine of the top seventeen slots in ranking of drug addiction and abuse.[46]
>
> **Drug Use** – The medical marijuana ballot-initiative states now occupy five of the top seven slots in terms of the rate of past-month drug use in the nation. Only Massachusetts and Vermont have higher rates than these five states (Alaska, Colorado, Oregon, Maine, and California), and Vermont has itself passed a medical marijuana ballot-initiative in the past year. All of the medical marijuana ballot-initiative states are at or significantly above the national average.[47]

Amici are concerned that the current medical marijuana initiatives compromise the protection of seriously and terminally ill patients by exposing them to an unapproved drug. So-called medical marijuana laws mask the proven health risks inherent in crude marijuana use, both

[46] Substance Abuse and Mental Health Services Administration. (2003) *Overview of Findings from the 2002 National Survey on Drug Use and Health* (Office of Applied Studies, NHSDA Series H-21, DHHS Publication No. SMA 03-3774). Rockville, MD

[47] Ibid.

in practice and in perception, and they compromise the safety and proper treatment of these patients. In contrast, we have *no* objection to any medicines that may evolve from the cannabinoids, including Marinol, provided that they are approved as safe and effective by the Food and Drug Administration under current federal law.

Amici are also concerned that legalization advocates' efforts to confuse the public about the difference between crude marijuana and the cannabinoids that scientists are studying for possible use in medicine, have contributed to the past decade's drop in the perception of marijuana's harm. This has resulted in an increase in marijuana use, other drug use, and drug addiction. The continued acceptance of the crude-marijuana-as-medicine concept will only worsen these problems.

CONCLUSION

Amici believe that it is critically important that the Supreme Court uphold the supremacy of the federal FDA regulatory process, and its carefully researched determination that there is no currently accepted medical use for crude, or home-grown, marijuana, and that therefore there can be no "medical use" exception to the Controlled Substances Act. Logically, then, the Appellate Court cannot create a distinct class of activities out of the "medical use" subgroup, and therefore the alleged medical use of marijuana is an activity which must come under the jurisdiction of the federal Controlled Substance Act, as authorized

by the Commerce Clause of the U.S. Constitution. Accordingly, the decision of the Appellate Court should be reversed.

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APPENDIX

TABLE 1

States That Have Passed Medical Marijuana Initiatives[49]

California
Proposition 21
The Compassionate Use Act of 1996

Arizona
Proposition 200
The Drug Medicalization, Prevention, and Control Act of 1996

Proposition 300
A 1998 initiative to reinstate certain provisions of proposition 200

Alaska
A 1998 Act Relating to the Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions

Colorado
Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions Passed in 1998, but invalidated by the Colorado Supreme Court for insufficient signatures.

Nevada
Medical Marijuana Initiative of 1998

Oregon
Oregon Medical Marijuana Act of 1998

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[49] National Families in Action: A Guide to Drug-Related State Ballot Initiatives, Initiative Index, www.nationalfamilies.org/guide/initiative_index.html.

Washington
Initiative 692
Medical Use of Marijuana Act of 1998

District of Columbia
Initiative 59
Legalization of Marijuana for Medical Treatment Initiative of 1998 Different sponsors but assisted by Americans for Medical Rights

Maine
A 1999 Act to Permit the Medical Use of Marijuana

Colorado
Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions Passed in 2000.

Nevada
Medical Marijuana Initiative of 2000
Second vote required to amend state constitution

TABLE 2

EXAMPLES OF NON-CANNABINOID MEDICATIONS AVAILABLE FOR NAUSEA ASSOCIATED WITH CANCER CHEMOTHERAPY

Serotonin Antagonists
Ondansetron (Zofran)
Granisetron (Kytril)
Tropisetron (Navoban)
Dolasetron

Phenothiazines:
Prochlorperazine (Compazine)
Chlorpromazine (Thorazine)
Thiethylperazine (Torecan)
Perphenazine (Trilafon)
Promethazine (Phenergan)

Corticosteroids
Dexamethasone (Decadron)
Methylprednisolone (Medrol)

Anticholinergics
Scopolamine (Trans Derm Scop)

Butyrophenones
Droperidol (Inapsine)
Haloperidol (Haldol)
Domperidone (Motilium)

Benzodiazepines
Lorazepam (Ativan)
Alprazolam (Xanax)

Substituted Benzamides
Metoclopramide (Reglan)
Trimethobenzamide (Tigan)
Alizapride (Plitican)
Cisapride (Propulsid)

Antihistamines
Diphenhydramine (Benedryl)

TABLE 3

Institute of Medicine Recommendations[50]

Recommendation 1: Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because different cannabinoids appear to have different effects, cannabinoid research should include, but not be restricted to, effects attributable to THC alone.

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[50] IOM Report, p. ES. 11.

Recommendation 2: Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.

Recommendation 3: Psychological effects of cannabinoids such as anxiety reduction and sedation, which can influence perceived medical benefits, should be evaluated in clinical trials.

Recommendation 4: Studies to define the individual health risks of smoking marijuana should be conducted, particularly among populations in which marijuana use is prevalent.

Recommendation 5: Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (less than six months); be conducted in patients with conditions for which there is reasonable expectation of efficacy; be approved by institutional review boards; and collect data about efficacy.

Recommendation 6: Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions:

- failure of all approved medications to provide relief has been documented,
- the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs,
- such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and

- involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

Note: Recommendations 5 and 6 are consistent with current FDA research guidelines. The IOM report cautions that "the purpose of clinical trials of smoked marijuana, using research-grade marihuana rather than street marijuana," "*would not be to develop marihuana as a licensed drug*, but such trials could be a first step towards the development of a rapid-onset, nonsmoked cannabinoid delivery system." (emphasis added) See our footnote 14.

1999 National Household Survey on Drug Abuse[1]

(Highlighted states have passed medical marijuana initiatives since 1996)

Percent Reporting Past-Year Drug Dependence

State	Ranking	Rate
Alaska	**1**	**2.8**
Nevada	**1**	**2.8**
New Mexico	2	2.7
Delaware	3	2.4
California	**4**	**2.3**
Oregon	**4**	**2.3**
District of Columbia	**5**	**2.2**
Washington	**6**	**2.1**
Rhode Island	6	2.1
Massachusetts	6	2.1
Arizona	**7**	**2.0**
Colorado	**7**	**2.0**
Utah	7	2.0
Vermont	7	2.0
Connecticut	8	1.9
Montana	8	1.9
Michigan	9	1.8
New Hampshire	9	1.8
New York	9	1.8
National Average		1.7
Kansas	10	1.7
Louisiana	10	1.7
Minnesota	10	1.7
Mississippi	10	1.7
New Jersey	10	1.7
Wyoming	10	1.7
Illinois	11	1.6
Indiana	11	1.6
Maryland	11	1.6
Missouri	11	1.6
Ohio	11	1.6
Wisconsin	11	1.6
Maine	**12**	**1.5**
Idaho	12	1.5
Georgia	12	1.5
North Carolina	12	1.5
North Dakota	12	1.5
Oklahoma	12	1.5
Pennsylvania	12	1.5
Tennessee	12	1.5
Alabama	13	1.4
Arkansas	13	1.4
Hawaii	13	1.4
Nebraska	13	1.4
South Carolina	13	1.4
South Dakota	13	1.4
Texas	13	1.4
Florida	14	1.3
Kentucky	14	1.3
Virginia	15	1.3
Iowa	16	1.2
West Virginia	16	1.2

Percent Reporting Past-Month Drug Use

State	Ranking	Rate
Alaska	**1**	**10.7**
Massachusetts	2	10.1
Nevada	**3**	**9.6**
Colorado	**4**	**9.3**
New Mexico	5	8.9
Rhode Island	6	8.7
Delaware	7	8.5
Washington	**8**	**8.4**
California	**9**	**8.3**
Michigan	10	8.0
Oregon	**11**	**7.7**
Montana	11	7.7
New Jersey	11	7.7
Connecticut	11	7.7
District of Columbia	**12**	**7.6**
Indiana	13	7.5
Wyoming	14	7.3
Arizona	**15**	**7.1**
Maine	**15**	**7.1**
Hawaii	15	7.1
New/ Hampshire	16	7.0
New York	16	7.0
Pennsylvania	16	7.0
Wisconsin	16	7.0
National Average		6.9
Illinois	17	6.9
Florida	18	6.8
Vermont	18	6.8
Minnesota	19	6.7
Missouri	20	6.6
Ohio	21	6.5
Idaho	22	6.4
North Carolina	23	6.3
Utah	24	6.2
Kentucky	25	6.0
South Dakota	25	6.0
Kansas	26	5.9
Georgia	27	5.8
Mississippi	27	5.8
Louisiana	28	5.7
Nebraska	29	5.6
Iowa	30	5.5
Tennessee	30	5.5
North Dakota	31	5.4
South Carolina	31	5.4
Texas	31	5.4
Maryland	32	5.3
Alabama	33	5.1
Oklahoma	33	5.1
West Virginia	33	5.1
Arkansas	34	5.0
Virginia	35	4.7

2002 National Household Survey on Drug Abuse[2]

(Highlighted states have passed medical marijuana initiatives since 1996)

Percent Reporting Past-Year Drug Dependence and Abuse		
State	Ranking	Rate
California	**1**	**2.9**
Nevada	**1**	**2.9**
Massachusetts	2	2.8
Washington	**2**	**2.8**
Vermont	3	2.7
Louisiana	3	2.7
Connecticut	3	2.7
Arizona	**4**	**2.6**
Colorado	**4**	**2.6**
Oregon	**4**	**2.6**
New Mexico	4	2.6
Delaware	4	2.6
District of Columbia	**5**	**2.5**
Alaska	**5**	**2.5**
New York	5	2.5
Montana	5	2.5
Maine	**6**	**2.4**
Maryland	6	2.4
Arkansas	6	2.4
New Hampshire	6	2.4
Tennessee	6	2.4
Illinois	6	2.4
Minnesota	7	2.3
Kentucky	7	2.3
Mississippi	7	2.3
Utah	7	2.3
National Average		2.25
Oklahoma	8	2.2
Michigan	8	2.2
Idaho	9	2.1
Rhode Island	10	2.0
Hawaii	10	2.0
Indiana	10	2.0
Texas	10	2.0
North Carolina	10	2.0
Georgia	10	2.0
Kansas	10	2.0
Wisconsin	10	2.0
Wyoming	10	2.0
West Virginia	10	2.0
Florida	11	1.9
Ohio	11	1.9
Alabama	12	1.8
Nebraska	12	1.8
New Jersey	12	1.8
Pennsylvania	12	1.8
South Carolina	13	1.7
South Dakota	13	1.7
Missouri	13	1.7
Virginia	14	1.6
North Dakota	14	1.6
Iowa	15	1.4

Percent Reporting Past-Month Drug Use		
State	Ranking	Rate
Massachusetts	1	10.7
Vermont	2	10.5
Alaska	**3**	**9.2**
Colorado	**3**	**9.3**
Oregon	**4**	**8.7**
Maine	**5**	**8.4**
California	**6**	**8.2**
Rhode Island	6	8.2
District of Columbia	**7**	**8.1**
New Hampshire	8	8.0
North Carolina	9	7.9
Washington	**10**	**7.7**
Delaware	11	7.6
Connecticut	12	7.5
Hawaii	12	7.5
Michigan	12	7.5
New Mexico	12	7.5
Nevada	**13**	**7.3**
Illinois	14	7.2
New York	15	6.8
National Average		6.7
Arizona	**16**	**6.7**
Arkansas	16	6.7
Kentucky	16	6.7
Louisiana	16	6.7
Minnesota	17	6.6
Wisconsin	18	6.3
Montana	18	6.3
Maryland	19	6.2
Tennessee	19	6.2
Georgia	20	6.1
Kansas	20	6.1
Florida	21	6.0
Pennsylvania	22	5.9
Ohio	22	5.9
New Jersey	23	5.8
Alabama	23	5.8
Wyoming	24	5.7
South Carolina	24	5.7
Missouri	24	5.7
Mississippi	24	5.7
Virginia	25	5.5
Oklahoma	26	5.4
Idaho	26	5.4
Texas	27	5.3
Indiana	28	5.2
West Virginaia	29	5.0
Utah	29	5.0
Nebraska	30	4.6
Iowa	31	4.5
South Dakota	31	4.5
North Dakota	32	4.1

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Supreme Court of The United States

JOHN ASHCROFT, ATTORNEY GENERAL ET AL.,

Petitioners,

- v -

ANGEL McCLARY RAICH, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

Brief of *Amici Curiae* Robert L. DuPont, M.D., Peter B. Bensinger and Herbert Kleber, M.D. in Support of Petitioners

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BRIEF OF *AMICI CURIAE*

This brief of *amici curiae* [1] is filed in support of Petitioner and is submitted on behalf of Robert L. DuPont, M.D., Peter B. Bensinger, Herbert Kleber, M.D., (herein referred to as "*amici*").

INTEREST OF AMICI CURIAE

Robert L. DuPont, M.D., was the first Director of the National Institute on Drug Abuse (NIDA) and the second Director of the White House Special Action Office for Drug Abuse Prevention, the initial White House drug abuse prevention "Czar" position. He is the author of The Selfish Brain -- Learning From Addiction, Clinical Professor of Psychiatry at Georgetown Medical School, President of the Institute for Behavior and Health, Inc. and Vice-president of Bensinger, DuPont and Associates.

Peter B. Bensinger served as Administrator of the U.S. Drug Enforcement Administration (1976 –1981), as a Representative of the U.S. Department of Justice Delegation to the regulator meetings of the U.N. Commission on Drugs, and as a Principal Delegate of the Department of Justice to INTERPOL.

Herbert Kleber, M.D., is Professor of Psychiatry and Director of the Division on Substance Abuse at the Columbia University College of Physicians and Surgeons. He served as the Deputy for Demand Reduction at the Office of National Drug Control Policy under Director William Bennett and President George H.W. Bush. Dr. Kleber has been a pioneer in the research and treatment of narcotic and cocaine abuse for over 35 years and is the author or co-author of more than 200 papers, chapters, and books dealing with all aspects of substance abuse.

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[1] Both parties have consented to the filing of this brief. The letters of consent have been filed with the Clerk of the Court. Counsel for a party did not author this brief in whole or in part. No person, entity, other than the *amici curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

SUMMARY OF ARGUMENT

This case is not what it appears. The Court of Appeals' ruling below—and the parties in their written arguments—have focused only on the effect that the activities in this case do (or do not) have on illegal interstate drug trafficking. But this case implicates issues that extend far beyond that narrow question—issues of enormous national significance. This case presents the Supreme Court with the opportunity to recognize and reinforce the United States' obligation to comply with international treaties, specifically, the Single Convention on Narcotic Drugs, 1961. It also enables this Court to underscore the appropriateness of the federal government's reliance on the Food and Drug Administration as the sole agency authorized to approve medical products as safe and effective for use within the United States.

The activities in this case, if allowed to proliferate across the country, would essentially eviscerate our comprehensive federal regulatory system governing the testing and use of medical products--a system that has been carefully crafted over the last century to protect patient health and safety. Such a proliferation would also force the United States for the first time to fall out of compliance with the unmistakable and very specific mandates of the Single Convention. If the Court of Appeals' ruling is allowed to stand, it will have widespread negative consequences for the enforcement of the comprehensive provisions of the Controlled Substances Act, and therefore for the implementation of the United States' obligations under the Single Convention. For these reasons, a*mici* have submitted this brief urging this Court to address these far-reaching questions.

ARGUMENT

I. The Treaty Power Provides a Separate and Independent Source of Congressional Power in This Case.

While Congress must certainly regulate in accordance with its enumerated powers, the Commerce Clause does not provide the sole source of congressional authority in this case. The United States may enter into treaties governing matters of international concern and impact. Such treaties, in conjunction with the federal Constitution and federal legislation, comprise the supreme law of the land. U.S. Const. Art. II, sec. 2. cl. 2 (power of the President to enter into treaties); U.S. Const. Art. VI, cl. 2. Congress has the power to enact all laws "necessary and proper for carrying into Execution…all…Powers granted by this Constitution." U.S. Const. Art. I, sec.8, cl.18. Accordingly, Congress has the power to enact laws implementing the United States' obligations under treaties to which the U.S. is a signatory. The Controlled Substances Act, 21 U.S.C. sec. 801 et seq. (1970), ("CSA") is such a law, and its regulation of the class of activity in this case is necessary to fulfill those obligations.

Federal laws, like the CSA, which implement U.S. treaty obligations, are unquestionably a valid exercise of congressional power, even in the face of conflicting state laws.[2] In *Missouri v. Holland,* 252 U.S. 416 (1920), this Court upheld the power of Congress to enact legislation, pursuant to a treaty, despite contrary state law. The Court stressed that such legislation--in that case the Migratory Bird Treaty Act--stands on a separate basis of congressional power, and rejected the argument that Congress must have independent constitutional authority separate from a treaty as a basis for enacting legislation. *Id.* at 432-33. The CSA's comprehensive regulatory structure, too, is supported by the Treaty Power, as well by Congress' authority under the Commerce Clause.

A. The Single Convention on Narcotic Drugs 1961 Governs the Nature and Scope of the United States' Obligations to Control Cannabis and Cannabis-Based Products.

The United States is a party to two treaties that govern the use of, and trade in, controlled substances for both medical and

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[2] Of course, such laws cannot transgress upon affirmative individual rights protected under the federal Constitution. However, such issues are not before the Court in this case.

non-medical purposes: the 1961 Single Convention on Narcotic Drugs (Single Convention),18 U.S.T. 1407 (1967), 520 U.N.T.S. 151 (1964), and the 1971 Convention on Psychotropic Substances (1971 Convention), 1019 U.N.T.S. 175 (1976), Treaty No. 14,596.[3] Cannabis[4] and cannabis-derived products are exclusively regulated by the Single Convention.

Official commentaries interpreting and explaining the two treaties support this conclusion. The 1971 Convention was intended to apply only to pure, generally synthetic, substances not already under the control of the 1961 Convention. See Office of the U.N. Secretary General (1973), *Commentary on the Single Convention on Narcotic Drugs 1961* ("1961 Commentary"), pp.87-88, para.7; Office of the U.N. Secretary General (1976), *Commentary on the Convention on Psychotropic Substances 1971* ("1971 Commentary"), p.37, para.9; p.394. Hence, this discussion of the Treaty Power will focus on the requirements of the Single Convention.[5]

B. Pursuant To the Single Convention, the United States Must Ensure That the Production and Use of Narcotic Substances Accords With the Scientific Standards Established By a Country's Normal Regulatory System.

The Single Convention was intended to simplify and replace existing treaties governing the control of narcotic substances. It imposes certain restrictions and controls on domestic manufacture, distribution, import/export, and possession of controlled substances, as well as on international trade. One fundamental principle animates the entire treaty fabric: the production **and use** of narcotic substances must be limited

[3] The United States is also a party to the 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which focuses primarily on the means of addressing and controlling international drug trafficking.

[4] The proper scientific name for the marijuana plant is *Cannabis sativa*.

[5] However, to the extent that the Court of Appeals' ruling would be broad enough to permit the manufacture and use of other controlled substances for personal medical purposes, the U.S.'s obligations under the 1971 Convention would support the validity of the Controlled Substances Act as applied to such activity as well. In 1978, Congress enacted the Psychotropic Substances Act, Pub.L.95-633, Nov. 10, 1978, 92 Stat. 278 (which became a part of the CSA), to coincide with the 1971 Convention, which entered into force in the U.S. on July 15, 1980.

exclusively to medical and scientific purposes. 1961 Convention, preamble, Art. 4(c). See also, 1971 Convention, preamble, Art. 5.

The treaty recognizes that, while addiction to narcotic drugs is a serious evil, the proper use of legitimate medical products is essential for the relief of pain and suffering. 1961 Convention, preamble. Accordingly, its provisions were structured to ensure that each Party could make new narcotic-containing medical products available to its citizens in a timely fashion. However, it is clear that, in order to comply with those provisions, a Party must require that the development and approval processes for such medicinal products meet the exacting standards of modern medicine. The CSA was scrupulously crafted to address and implement these requirements, as well as every other aspect of the controls mandated by the treaty.

The treaty was promulgated at a time when governmental regulatory bodies, such as the United States Food and Drug Administration, were imposing strict controls on the quality and safety of medical products. The need for the practice of medicine to be "evidence-based" had become well-established, particularly in the Western world. For several decades, scientists had been conducting randomized, placebo-controlled clinical trials to investigate the safety and efficacy of investigational medical products. Chow, S. and Liu, J., *Design and Analysis of Clinical Trials*, p. 4 (1998). Then, as now, the results of such clinical trials formed the basis both of governmental regulators' marketing approvals and physicians' prescribing practices. See Guyatt, G. et al., "Evidence Based Medicine: Principles for Applying the Users' Guides to Patient Care," 284 *Journal of the American Medical Association* 1290 (Sept. 13, 2000). The Single Convention recognized that different countries may have different regulatory systems. See 1961 Commentary, Art.4, para.12, p. 111 ("legitimate" existing systems of indigenous medicine may be taken into account). However, it contemplated that each Party would employ its **conventional** regulatory standards when determining whether, and which, narcotic substances and products could be made available for medical use. Nowhere in the treaty is there any suggestion that a Party may allow a diluted or informal "medical" system solely for specific controlled substances.

Furthermore, at the time of the Single Convention, crude narcotic plant material was not considered suitable for medical use. For example, opium smoking and coca leaf chewing were not accepted methods for delivering the therapeutically useful

components contained within the herbal material. Only processed and refined botanical extracts could constitute a medicinal product.[6] Indeed, by the 1850s, the medicinal use of pure alkaloids, rather than crude opium preparations, was common in Europe. Department of Justice, Drug Enforcement Administration, "Opium Poppy Cultivation and Heroin Processing in Southeast Asia," (March 2001) at p. 2, www.usdoj.gov/dea/pubs/intel/20026/20026.html (accessed July 28, 2004) (hereafter "DEA Opium Report").

This was also true with regard to crude herbal cannabis. Cannabis had not been adequately refined into a genuine pharmaceutical product, standardized for composition and dosage, and tested in controlled clinical trials. In 1954, the World Health Organization (WHO) had determined that, on existing scientific evidence, herbal cannabis and crude cannabis preparations were obsolete and did not have current medical usefulness. Wooton, "Report On Cannabis," *Report of the Hallucinogens Subcommittee to the Advisory Committee on Drug Dependence*, appen. 2 (1967). Following the WHO determination, the Single Convention, for the first time, imposed obligations on signatories to bring **domestic cultivation and possession** of cannabis under specific controls.

The International Narcotics Control Board (INCB) has recently confirmed that a Party **may not** allow cannabis to be cultivated, manufactured, and used for medical purposes **unless** such products have satisfied the rigorous regulatory standards that apply to other medical products. Such use must be supported by objective scientific data from properly-conducted research studies and otherwise accord with principles of modern medicine:

> The Board notes that the Governments of Canada and the Netherlands have decided to authorize the medical use of cannabis, although no **conclusive results** concerning the possible therapeutic properties and medical uses of cannabis have been obtained from the research conducted in those countries or anywhere else. The Board calls on Governments to consider the scheduling status of

[6] The treaty defines "medicinal opium" as the "coagulated juice of the opium poppy" that "has undergone the processes necessary to adapt if for medicine use." Art. 1 (o), (p). Moreover, only licensed manufacturers were allowed to produce such a medicinal product. See discussion in text below.

> cannabis, which is listed in Schedules I and IV of the 1961 Convention, and not to allow its medical use unless **conclusive results of research** are available indicating its medical usefulness. The Board requests Governments to then ensure that such use is in line with **general principles guiding sound medical use and practice**.

INCB, *Report 2002*, at p. 21 (2003) (emphasis added).

Recent UK research demonstrates that it is possible for a country to fulfill this mandate, while still making cannabis-based medical products available to patients in a reasonably timely manner. See, Wade, D., *et al.*, "A Preliminary Controlled Study to Determine Whether Whole-Plant Cannabis Extracts Can Improve Intractable Neurogenic Symptoms," 17 *Clinical Rehabilitation* 18 (2003). The CSA, by seeking to require that cannabis and cannabis-based products can be produced and used by patients **only if** such products meet existing regulatory standards for quality, safety, and efficacy, falls squarely in line with such efforts.

C. By Prohibiting All Individual Production and Use of Cannabis Outside the Bounds of the Established Regulatory System, the Controlled Substances Act Accords With the Single Convention's System of Control.

The Single Convention categorizes controlled substances into one of four schedules. These international schedules should not be confused with the schedules that a nation, such as the U.S., may choose to incorporate into its domestic law. For example, unlike Schedule I of the CSA, Schedule I of the Single Convention is not the most restrictive. Rather, it establishes requirements and restrictions that apply to most controlled substances.[7]

Schedule IV is the "strictest" schedule under the Single Convention. Under the treaty, crude cannabis[8] and cannabis resin[9]

[7] The Convention uses the term "drugs." The term "drugs," in turn, is defined as "any of the substances in Schedules I and II, whether natural or synthetic." The controls imposed on Schedule II drugs are virtually the same as those under Schedule I, with only a few exceptions. The requirements of Schedule III are less stringent, but they apply only to specific preparations of drugs.

[8] Cannabis is defined in the Convention as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the

are contained in Schedule IV.[10] The treaty contemplated that Schedule IV drugs would not be used in medical practice unless they had therapeutic benefits not offered by other drugs. INCB, Report 2002 at p. 21 (2003). With regard to such drugs, a Party **must** take the following actions (in addition to the controls imposed by Schedule I):

- 1) adopt any special measures of control **that in its opinion** are necessary, having regard to the particularly dangerous properties of the drug; and
- 2) ***if in its opinion*** **the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare**, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drugs **except for** amounts which may be necessary to medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.

Art. 2(5). Therefore, if a Party **in good faith** believes that it must impose certain controls on a substance in Schedule IV in order to protect public health and welfare, that Party has an obligation under the treaty to implement such controls. 1961 Commentary, Art. 2, para.4, p. 65. Congress, in enacting the CSA, could rationally have concluded that its system of controls was required in the case of cannabis (and other controlled substances) to ensure that only legitimate medical products reach the hands of individual patients.

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tops) from which the resin has not been extracted, by whatever name they may be designated."

[9] Cannabis resin is defined in the Convention as "the separated resin, whether crude or purified, obtained from the cannabis plant."

[10] All drugs listed in Schedule IV must also be listed in, and subject to the controls attendant upon, Schedule I. Hence, it is this **joint placement** in Schedules IV and I that imposes the greatest degree of control under the Convention. Cannabis extracts and tinctures, which have undergone some degree of processing and refining, are listed only in Schedule I.

1. The Treaty Specifically Requires Parties to Impose Strict and Very Specific Domestic Controls on Crude Herbal Cannabis.

In addition to the Schedule IV admonitions, the treaty specifically imposes severe and very specific restrictions on the cultivation of cannabis, opium, and coca. Indeed, Article 22 **requires** a Party **to prohibit cultivation**, ***if*** the Party concludes in good faith that the "prevailing conditions" in the country make such prohibition the most suitable measure of protecting the public health and safety. Furthermore, a Party that prohibits such cultivation must "take appropriate measures" to seize **and destroy** any plants that are illegally cultivated, except for small quantities that **the Party** itself may need for scientific or research purposes.[11]

If a Party does choose to **permit** cultivation of the cannabis plant, opium poppy, or coca bush, the Party must, under Article 23, establish and maintain a national Agency to carry out the Party's obligations. See also Art. 26 (coca bush), 28 (cannabis plant). Article 23 requires that **only** nationally-licensed cultivators, whose license specifically identifies the precise extent and location of the land that they are authorized to cultivate, may grow such narcotic plants, and they must deliver their total crops to the Agency.[12]

Only the Agency may deal with such crops. The Agency must have the **exclusive right** of importing, exporting, wholesale trading, and maintaining stocks.[13] **However**, in recognition of the importance of facilitating legitimate pharmaceutical development, the treaty does make a clear exception for those stocks held by manufacturers of extracts, alkaloids, or preparations that the manufacturer will use to produce a pharmaceutical product. Indeed, the Parties are not required to extend the agency's exclusive rights either to such raw materials or to partially processed materials that will be used in the manufacture of a finished pharmaceutical product.

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[11] This section conspicuously fails to include "medical use."

[12] The Agency must purchase and take physical possession of such crops as soon as possible, but, in the case of opium and cannabis, not later than four months after the end of the harvest.

[13] The United States has established such an Agency in the National Institute on Drug Abuse, which has contracted with the University of Mississippi to cultivate herbal cannabis for research purposes.

There is no doubt, in light of the other control provisions of the treaty generally applying to Schedule I (of the treaty) substances, that this last exception for "manufacturers" was **not** intended to apply to, or authorize, individuals to cultivate cannabis (or opium or coca) in their backyards and transform it into baked goods, teas, or other homemade concoctions. The specific controls imposed on cultivation, coupled with the treaty's overarching controls on all narcotic substances, demonstrate that **all** manufacture[14] and distribution must be conducted by licensed and regulated entities that are producing standardized products for medical or research purposes.[15] Therefore, were the U.S. to permit individuals, in various States across the country, to cultivate cannabis or other narcotics for personal medical use, the U.S. would be in violation of these unmistakably clear treaty obligations.

In addition to these controls, the Single Convention, in an effort to prevent legitimate medical products from being diverted to illicit use, imposes strict requirements on Parties to provide annual estimates regarding quantities of drugs utilized or held for specific purposes, Art. 19, as well as statistical returns concerning, among other things, production, manufacture, consumption, imports/exports, seizures/disposals, and year end stocks. Art. 20. These requirements apply even to substances used in research. INCB, *Narcotic Drugs* 2002 at p. 97 (2003) (recognizing appropriateness of UK reporting of amounts of cannabis extracts

[14] "Production" means the separation of opium, coca leaves, cannabis and cannabis resin from the plant. "Manufacture" means all processes by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs. Art. 1(n), (t).

[15] The treaty obligates the US and other parties to **license and control *all*** persons and entities engaged in the manufacture of narcotic substances and products, as well as to control under license the premises where such manufacture takes place. In addition, those manufacturers must obtain "periodical permits" indicating the kinds and amounts of drugs they are authorized to manufacture. Art. 29. The Party must also control **all** persons and entities distributing such substances and license the premises in which such distribution takes place. Art. 30. Finally, the Parties must require all licensees to have adequate **qualifications**. Art. 34(a). They must also require all manufacturers, traders, scientists, scientific institutions and hospitals to keep records for two years showing 1) the quantities of each drug manufactured and 2) each individual acquisition and disposal of drugs. Art. 34(b). The Parties are also obligated to impose specific requirements and restrictions on the labeling and import/export of a medication. See Art. 30-31. The provisions of the CSA, in conjunction with those of the Food, Drug & Cosmetic Act, satisfy these obligations.

used for medical research). Even if an individual practitioner or scientist wishes to conduct a small study using cannabis or some other narcotic substance, the Party must ensure that those small amounts are accounted for through the estimate and statistical return system. If individuals (in any State authorizing it) could cultivate and possess cannabis (or some other narcotic) on a physician's advice, this entire system would rapidly become disrupted and meaningless.

The Single Convention also controls the means by which **individual patients** may obtain and possess narcotic substances for medical use. The treaty dictates that narcotic substances may only be supplied or dispensed to individuals on prescription, except to the extent that physicians may lawfully obtain, use, dispense or administer such substances in connection with their "duly authorized" therapeutic functions. Art. 30(2)(b). Furthermore, a Party may permit the **possession** of such substances **only "under legal authority**." Art. 33. The mere fact that a State may authorize a physician to "recommend" the use of a crude cannabis product—one that he/she can neither prescribe nor dispense under either state or federal law—would not be sufficient to meet the United States' treaty obligations.[16]

Thus, it is apparent that the Single Convention imposes obligations on the United States comprehensively to control cannabis, from the point of its cultivation through its ultimate possession and use by individuals for medical purposes. The CSA, by requiring that cannabis and cannabis-based products meet rigorous scientific criteria for quality, safety, and efficacy, satisfies these obligations.

2. The Overarching Purpose of the CSA is Much Broader Than the Prohibition and Control of Illegal "Drug Trafficking."

The CSA establishes a comprehensive scheme that 1) provides a mechanism (the scheduling process) by which the results of scientific research may be used to support the approval and availability of new pharmaceutical products containing controlled substances; and 2) reduces the likelihood that controlled substances or products will be diverted to nonmedical use. As a

[16] Under the Controlled Substances Act, a prescription is only valid if the **issuing physician has authority to dispense** the drug. 21 U.S.C. sec. 353(b).

necessary part of that scheme, the CSA places controlled substances in one of five schedules, depending on the substance's recognized therapeutic usefulness, safety for use under medical supervision, and abuse liability. Other provisions of the CSA regulate and control the manufacture, import/export, distribution, research, and possession of controlled substances which will generally form a part of pharmaceutical products approved by the Food and Drug Administration.

The Court of Appeals in this case found that, by enacting the Controlled Substances Act, Congress was "primarily concerned with the trafficking or distribution of controlled substances." *Raich v. Ashcroft*, 352 F3d. 1222, 1232 (9th Cir. 2003). Repeatedly, the Court stressed that the intrastate, noncommercial use of cannabis for personal medical use on the advice of a physician and in accordance with state law would not have a substantial effect on interstate "drug trafficking." With all due respect, the Court of Appeals' view of the CSA is far too narrow. As indicated above, the purposes of the CSA go far beyond the prohibition, prevention, and punishment of the illegal trade in drugs.

The CSA was enacted shortly after, and in response to, the United States' 1967 ratification of the Single Convention. The congressional findings unquestionably reflect that fact.[17] Congress found, among other things, that: "The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances." 21 U.S.C. sec. 801(7) (findings).[18]

The structure of the CSA demonstrates that Congress was seeking, in accordance with the Single Convention, to ensure that narcotic and other psychoactive substances are manufactured, traded, **and used** only for medical and scientific purposes. The

[17] See also, congressional findings establishing the role of the CSA in satisfying the United States' obligations under the 1971 Convention. 21 U.S.C. sec. 801a.

[18] In light of the comprehensive domestic controls required by the Single Convention, the term "traffic" can be interpreted to include all cultivation, manufacture, delivery or distribution (constructive or actual), and ultimate possession of a "medical" product containing a narcotic substance, even where such activities are conducted within a State. In 1969, in *U.S. v. Leary*, 395 U.S. 6 (1969), this Court invalidated an aspect of the Marijuana Tax Act, 26 U.S.C. sec. 4741 *et seq.*, as violative of the constitutional privilege against self-incrimination. Hence, the United States had an additional need to enact federal legislation regulating individual possession of cannabis, in order to meet its treaty obligations.

CSA is keyed to comport with the requirements of the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. sec 301 *et seq.*, that objective scientific data must determine which products should be considered appropriate and available for medical use. Congress could certainly have rationally determined that the CSA's (and FDCA's) standards and criteria, as well as its prohibitions, were necessary to fulfill the United States' obligations under the Single Convention.

This is further demonstrated by the role that the Single Convention plays in the rescheduling of substances under the CSA. The CSA establishes a rulemaking procedure by which the Attorney General may schedule a substance or transfer ("reschedule") a substance between schedules. 21 U.S.C. sec.811. The Attorney General must make specific findings relating to the relevant schedule. Before doing so, the Attorney General must request, from the Secretary of Health and Human Services, a medical and scientific evaluation of, and recommendations upon, certain statutory criteria relating to scientific knowledge, pharmacological effect, and abuse potential. These recommendations are binding on the Attorney General as to scientific and medical matters. **However**, if control is required by the United States' obligations under international treaties, the Attorney General must issue an order controlling the drug under the schedule he/she deems most appropriate to carry out such obligations, without regard to any of the findings described above. 21 U.S.C. sec.811.[19] This section demonstrates Congress' clear awareness that the availability of a medical product containing a controlled substance must be governed by the U.S.'s obligations under international treaties.

II. The Commerce Clause Provides a Firm Basis for the Application of the CSA to the Activities at Issue in This Case.

Over the last century, the United States has developed one of the most stringent pharmaceutical regulatory systems in the world. That system governs all aspects of the pharmaceutical development process, including products containing controlled substances. The Food, Drug, and Cosmetic Act (FDCA) utilizes exacting scientific criteria and standards to ensure that patients

[19] See *NORML v. DEA*, 559 F.2d 735 (D.C.Cir.1977) for a description of the rulemaking procedure that this section permits.

receive medications that are safe and efficacious for their intended use. The standards and criteria of the CSA, which coordinate with those of the FDCA, determine the circumstances under which a controlled substance with abuse potential may, when properly formulated, tested, and delivered as a pharmaceutical product, be made available as a prescription medicine. The Court of Appeals' ruling will subvert this integrated system, thereby adversely affecting interstate commerce in legitimate medical products and threatening harm to public health and safety.

A. The Court of Appeals' Ruling is Not Consistent with This Court's Recent Commerce Clause Jurisprudence.

The CSA's prohibition against unauthorized manufacture, distribution, and possession of controlled substances differs significantly from those federal laws at issue in recent Commerce Clause cases decided by this Court. In those cases, Congress had attempted to enact narrow, targeted legislation to punish, and thereby deter, the commission of specific types of crimes of violence. See *U.S. v. Lopez*, 514 U.S. 549 (1995) (federal criminal prosecution under Gun-Free School Zones Act, prohibiting the possession of a firearm in a school zone); *U.S. v. Morrison*, 529 U.S. 598 (2000) (federal civil remedy under Violence Against Women Act). Such legislation, this Court determined, directly infringed on the States' police power--an area in which States have been traditionally sovereign.

By contrast, the CSA is not such targeted legislation, nor is punishment of local intrastate crime its primary focus. Rather, the CSA, in conjunction with the FDCA, comprises a comprehensive federal system that regulates all aspects of pharmaceutical products containing controlled substances, as well as illegal trafficking in licit and illicit substances. In *Lopez*, this Court emphasized that the criminal statute in that case was "not an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." 514 U.S. at 561. The CSA's and FDCA's comprehensive regulation of pharmaceutical products, from initial manufacture (including cultivation) to individual use by patients, is essential to ensure that only safe and effective, i.e., standardized and tested, products are made available to patients and their physicians. The Court of Appeals' ruling in this case will unquestionably undercut that regulatory system.

1. The Determination of W*hich* Medical Products Can be Made Available for Medical Use is Not an Area Traditionally Reserved to the States, Particularly if Those Products Contain Controlled Substances.

The "practice of medicine," i.e., a physician's methods of diagnosis, assessment, documentation, monitoring, and follow-up, have traditionally fallen within the purview of State regulation. However, since the beginning of the 20th century, the federal government has had the primary responsibility for the **regulation of medical products, particularly those containing controlled substances**.[20] Often the states have acted to create parallel systems—sometimes only in the wake of federal legislation. Often that federal legislation has directly affected the practice of medicine, and in some areas, has been the exclusive source of the parameters of professional practice.[21]

Our federal regulatory system has developed in response to serious threats to patient health and safety. In 1900, medical products were essentially unregulated. Many "patent" medicines contained significant amounts of opium, cocaine, alcohol, and cannabis. "Accidental" addiction became a serious problem. See Whitebread, C., "The History of the Non-Medical Use of Drugs in the United States," (speech to the California Judges Association

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[20] The Court of Appeals has itself recognized that the federal government can lawfully impose constraints on a physician's practice in cases involving the use of cannabis for alleged medical purposes. While the First Amendment protects a physician's right to provide medical information and advice about cannabis for a number of legitimate purposes, a physician can be subject to federal sanction if he/she provides such advice deliberately to enable the patient to obtain cannabis. See *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002), *cert. denied*, 124 S.Ct. 387 (2003). This Court need not decide whether a State may determine that an FDA-approved medical product may be prescribed by physicians for a specific "off-label" use. See *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004) (CSA does not apply to prescription issued by physician to enable competent, terminally ill patient to end his/her life, as authorized by State law).

[21] For example, in order to dispense narcotics to addicted patients for purposes of maintenance or detoxification, a physician must be specially licensed as an opiate treatment program. See 21 U.S.C. sec. 823(g). Under the recent Drug Abuse Treatment Act, 21 U.S.C. sec. 823(g), physicians who do not obtain such a registration may, subject to a number of requirements, prescribe to patients narcotic products in Schedules III-V, if such products have been approved by the FDA for treatment of addiction. See 21 U.S.C. sec. 823(g)(2).

1995). When the States failed adequately to address the problem, Congress acted by passing the Food and Drug Act, Act June 30, 1906, c.3915, 34 Stat.768, which required, among other things, that medications indicate on the label the quantity of alcohol, morphine, opium, cocaine, heroin, or cannabis that they contained.[22]

Over the following decades, federal legislation was gradually expanded to address various abusive practices or, unfortunately, events involving significant suffering and harm. For example, the Elixir Sulfanilamide disaster led to the enactment of the 1938 Food, Drug & Cosmetic Act (FDCA), Act June 25, 1938, c.675, 52 Stat. 1040, which required, among other things, that new drugs be tested for safety before marketing. The thalidomide tragedy in Europe led to the passage of the Drug Amendments of 1962, Pub.L.87-781, sec. 1, Oct. 10, 1962, 76 Stat. 780 (also known as the Kefauver-Harris Amendments), which required that products be proved to be both safe and effective before marketing. Since that time, Congress has enacted numerous additional federal laws governing multiple aspects of medical products and controlled substances, among them the CSA.[23]

Across the United States, the FDCA's criteria became the "gold standard" for the quality, safety, and efficacy of medical

[22] While new cases of accidental addiction waned following the Act, many physicians felt obligated, as a part of their medical practice, to prescribe controlled substances to those unfortunate individuals who had become addicted. Congress rejected the concept that such prescribing constituted the legitimate practice of medicine and, in 1914, enacted the Harrison Narcotics Act, 38 Stat. 785, Comp. St. sec 6287g-6287q (1914), *as amended* 26 U.S.C. 4701-36. The Harrison Act, although ostensibly a revenue measure founded on the Taxing Power, essentially precluded the prescription of opiates to addicts for maintenance purposes. In 1937, the Marihuana Tax Act, 26 U.S.C. sec. 4741-76, created strong disincentives for physicians prescribing cannabis, thereby effectively making it unavailable for medical use. These acts were replaced by the CSA.

[23] The FDCA maintained significant control over controlled substances until 1968, when all federal drug control was consolidated under the Department of Justice. The Drug Abuse Control Amendments of 1965 (DACA), Pub.L.89-74, July 15, 1965, 79 Stat. 226 , 21 U.S.C. sec. 360a, which were founded on the Commerce Clause, imposed restrictions and prohibitions on the **intra- or interstate** manufacture, sale, delivery, disposal, or possession of depressants, stimulants, and hallucinogens. *White v. U.S.*, 399 F.2d 813, 822 (8th Cir. 1968). Although DACA contained an exception for personal use, by the time of the CSA's enactment, the United States was obliged by the Single Convention to extend its system of controls to local/individual manufacture, possession and use of controlled substances.

products. Recognizing the importance of such stringent standards and procedures, States established similar regulatory systems to govern **those few products** that were manufactured, distributed, and sold only within a single state. For example, California enacted the Sherman Food, Drug, & Cosmetic Law ("Sherman Law"), Calif. Health & Safety Code sec. 109875 *et seq*. The Sherman Law requires that, in order to be approved as a medical product, a "new drug" must meet exacting scientific standards parallel to those established under the FDCA. See Kizer, K., "New State Program Puts Experimental Drugs on Fast Track," *California Physician* (Dec. 1988) (describing procedures and standards).

An intrastate investigational product may satisfy **either** the FDCA or state law. The Sherman Law prohibits **any person** from selling, delivering, or giving away any new drug unless either the FDA **or** the California Department of Health Services ("Department") has approved the drug for marketing. Calif. Health & Safety Code sec.111550. Physicians wishing to conduct clinical research with such drugs may do so only under an investigational new drug application filed with the FDA **or** with the Department. Calif. Health & Safety Code sec. 111590-95. Similarly, following the enactment of the CSA, many states adopted the Uniform Controlled Substances Act, which was directly modeled upon the CSA's provisions. California was among those states. See Calif. Health & Safety Code sec. 11000 *et seq*. The California Uniform Controlled Substances Act, like the CSA, placed cannabis in Schedule I. Calif. Health & Safety Code sec. 11054(d)(13).

When these systems work together in concert, patient protection is maximized. Because of their smaller size and greater flexibility, States may be able to sponsor research and move forward with the development of important pharmaceutical products more quickly than the FDA. See Kizer, *supra*. By contrast, a State may wish to maintain greater restrictions on pharmaceutical products containing controlled substances than those imposed under federal law.[24] However, if States permit unstructured and ungovernable systems to flourish within their borders, this synergy will quickly collapse, and the federal regulatory structure will be irreparably harmed.

[24] For example, while the branded product Marinol, which contains synthetic tetrahydrocannabinol (THC),[24] was rescheduled in 1999 to Schedule III of the CSA, see 64 Fed. Reg. 35928 (July 2, 1999), it was not rescheduled under California law until 2000 and in other states even later.

2. Instead of Providing Useful and Objective Scientific Data, California's Approach Will Undermine the Protections of the Food, Drug, and Cosmetic Act.

Our federal system is designed such that, in many areas, individual states "may serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Lieberman*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). However, the State of California has **not** attempted to establish a system designed to generate new and usable scientific data that could lead to a meaningful assessment of the future of cannabis or cannabis-based medical products.[25] It did not amend the Sherman Law. Indeed, the State did not remove cannabis from Schedule I of its own controlled substances law. Rather, by enacting Proposition 215, the California Compassionate Use Act of 1996 (CCUA), Calif. Health & Safety Code sec. 11362.5, the State merely abrogated certain of its own criminal laws as they applied to seriously ill patients who cultivate and/or possess cannabis for personal medical use on the advice of their physicians. [26] The CCUA authorizes patients to use any type of cannabis or cannabis products they wish, including hashish. Ops.Cal.Atty.Gen. No.03-411 (2003).

[25] The State of California did for three years make $3 million/year (which has now lapsed) available to researchers wishing to investigate the safety and efficacy of cannabis and cannabis-based products. See "The Marijuana Research Act of 1999," Calif. Health & Safety Code sec. 11362.9. This research has been conducted under the auspices of the Center for Medicinal Cannabis Research (CMCR) at the University of California San Diego. After funding 13 clinical trials using crude herbal cannabis obtained from the University of Mississippi, CMCR has apparently determined that future research, if it is to lead to a prescribable medical product, must involve purified cannabis administered through alternative, nonsmoked delivery systems, as well as synthetic cannabinoids. See CMCR, "Future Directions in Cannabinoid Therapeutics II: From the Bench to the Clinic" (workshop description) (June 27, 2004, Paestum, Italy), www.cmcr.ucsd.edu (accessed July 28, 2004). Advocates for herbal cannabis have criticized the CMCR for deviating from research involving "the crude plant that grows in the crude soil." Gardner, F., "The Politics of Marijuana: Cannabinoid Therapeutics," *CounterPunch* (July 17/18, 2004).

[26] California recently enacted legislation to clarify the provisions of the CCUA, make its application uniform across the state, and authorize a voluntary identification card system. Calif. Health & Safety Code sec. 11362.7 *et seq*.

Herbal cannabis (like herbal opium) is not a homogeneous substance. There are multiple strains of cannabis of varying cannabinoid composition that can be cultivated; different dosage forms --inhaled (smoked or vaporized), orally consumed (baked goods, candies, teas, or tinctures), transdermal (pastes or salves)-- that a patient may choose; and various amounts of active components that those dosage forms may deliver. Consequently, there is no possible way that the use of such unregulated products by patients throughout California will result in meaningful data that could answer the question: can cannabis or cannabis-based products satisfy modern scientific standards of quality, safety, and efficacy, and, if so, which specific product would be appropriate for which medical conditions?[27] For these reasons, major medical and healthcare organizations have not supported such state laws and initiatives. See, e.g., American Medical Association, Council on Scientific Affairs, Report A-01, "Medical Marijuana" (2001), www.ama-assn.org/ama/pub/article/print/2036-6124.html (calling for further adequate and well-controlled studies) (accessed July 28, 2004).

This action by the state of California did not create a "novel social and economic experiment," but rather chaos in the scientific and medical communities. Furthermore, under Court of Appeals ruling, such informal State systems could be replicated, and even expanded, in a manner that puts at risk the critical protections so carefully crafted under the national food and drug legislation of the 20th century.

3. The Controlled Substances Act, in Conjunction with the Food, Drug, and Cosmetic Act, Establishes a Comprehensive System of Regulation That Must, If Its

[27] There is, for that reason, complete uncertainty regarding how much cannabis a patient should be allowed to cultivate or possess for personal use. Compare Calif. Health & Safety Code sec. 11362.77 (allowing possession of eight ounces per patient) with Whitten, L., "Medical Marijuana Limits OK'd," *The Eureka Reporter* (July 15, 2004)(county ordinance allowing a patient to cultivate, possess, and consume three pounds of dried cannabis per year). Thus, in many cases the question arises as to whether an individual is cultivating cannabis for non-medical, as well as medical, purposes. The Court of Appeals' ruling would therefore mean that often the enforceability of the CSA would have to be litigated on a case-by-case basis.

Integrity is to be Maintained, Regulate the Activity at Issue in This Case.

The Food, Drug, and Cosmetic Act has established rigorous criteria to determine when a substance or product has been sufficiently studied and tested to justify its use by individual patients. The Controlled Substances Act employs similar standards to ensure that a product containing a controlled substance will be used by patients only when that use is supported by good scientific evidence. Accordingly, the Drug Enforcement Administration (DEA) looks to objective evidence when determining whether or not to move a substance from Schedule I to Schedule II. In an administrative rulemaking proceeding involving cannabis, the DEA Administrator has stated that he/she will examine the following factors in determining whether Schedule I substances such as cannabis, or a specific product[28] containing such substances, has a "currently accepted medical use":

1. The drug's chemistry must be known and reproducible;
2. There must be adequate safety studies;
3. There must be adequate and well-controlled studies proving efficacy;
4. The drug must be accepted by qualified experts; and
5. The scientific evidence must be widely available.

See 57 Fed.Reg. 10499,10506 (March 26, 1992). The DEA's use of these factors was upheld by the federal courts. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C.Cir. 1994).

The Drug Enforcement Administration and the Food and Drug Administration, in a recent rejection of another herbal cannabis rescheduling petition, stressed that the different strains of the cannabis plant can vary in composition and that such strains will have different effects on the human body. Different delivery forms will also have different effects. The FDA specifically stated that "there are many variables that can influence the strength,

[28] As indicated above, a bulk substance can remain in Schedule I, while a specific product (containing such a substance), that has been formulated and tested, can be placed in a lower schedule.

quality, and purity of marijuana as a botanical substance." Therefore, the agency stressed:

> The agency cannot conclude that marijuana has an acceptable level of safety without assurance of a consistent and predictable potency and without proof that the substance is free of contamination. If marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing and specifications of marijuana must be developed.

DEA, Notice of Denial of Petition, 66 Fed. Reg. 20038, 20045 (April 18, 2001).

Recent research in the United Kingdom has demonstrated that it is possible to develop a cannabis-based medical product that satisfies such stringent regulatory standards. However, that process is very challenging. The UK pharmaceutical development program cultivates specific cannabis strains in computer controlled greenhouses. Those strains are propagated by clones to maintain the plants' unique cannabinoid ratios. All aspects of the cultivation and harvesting process are standardized and strictly controlled. The pharmacologically active components of the plants are extracted by means of a proprietary and quality-controlled process. The extracts are carefully formulated with standard excipients into a conventional nonsmoked pharmaceutical dosage form (an oromucosal spray), which delivers a precise dose in each dosing increment. See Russo, E., *Cannabis: From Pariah to Prescription* (2003); Guy, G., and Whittle, B., "Prospects for New Cannabis-Based Prescription Medicines," 1 *Journal of Cannabis Therapeutics* 183 (2001); Notcutt, W., "Initial Experiments With Medicinal Extracts of Cannabis for Chronic Pain: Results From 34 'N of 1' Studies," 59 *Anaesthesia* 440 (2004).

The UK clinical research has involved over 1400 patients and has shown promising results in spasticity in multiple sclerosis and in certain types of neuropathic pain. The product's marketing application has been under consideration by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for 16 months, as each aspect of the product dossier is carefully examined and assessed.

The U.S. government has apparently expressed interest in such a program. See Johnson-Skinner, D., "New Drug Could

Affect Debate on Medical Pot," *The Hill* (Feb. 24, 2004). So, too, have leading physicians. See DuPont, R., Testimony Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, "Marijuana and Medicine: The Need for a Science-Based Approach," (April 1, 2004).[29] Surely the United States, through the CSA and the FDCA, must have the power to conclude that, if a cannabis-based botanical product is to be used for medical purposes, it must be similarly standardized for quality, safety and efficacy.[30] However, the Court of Appeals' ruling would effectively disable the federal government from being able to enforce such a requirement.

B. The Court of Appeals' Ruling Will Authorize an Underground "Medical" System That Will Adversely Affect Federal Regulation of Pharmaceutical Products, and Thereby, Interstate Commerce.

The Court of Appeals stated that its holding was "sufficiently narrow" to avoid concerns that it would "significantly undermine the FDA drug approval process." However, the Court's ruling, rather than being narrow, has the potential to authorize a vast, underground "medical" system that will substantially and adversely affect the protections afforded by that process.

1. Under the Court of Appeals' Ruling, Congress Would be Disabled From Acting Even in States That Have Not Authorized the Use of Cannabis for Medical Purposes.

The Court of Appeals ruled that intrastate cultivation and possession of cannabis for personal medical use on the advice of a physician did not affect interstate commerce **if** those activities were authorized by State law. However, if Congress is disabled from regulating an activity because it falls within an area of state sovereign power—an area "traditionally left to the states to

[29] Dr. DuPont is a former Director of the National Institute on Drug Abuse.

[30] The FDA does not foreclose the possibility that an approvable pharmaceutical product can be botanically-derived if properly manufactured, tested, formulated, and delivered. U.S. Department of Health & Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, "Guidance for Industry: Botanical Drug Products," (June 2004), www.fda.gov/cder/guidance/index.htm (accessed July 28, 2004).

regulate"--then in principle each State would be free to determine **how** it wishes to exercise that power to regulate. For example, in *Lopez*, this Court emphasized that, while over 40 states had enacted criminal laws outlawing the possession of firearms on or near school grounds, some states might choose other means of addressing the issue: "Other, more practical means to rid the schools of guns may be thought by the citizens of some State to be preferable for the safety and welfare of the schools those States are charged with maintaining." 514 U.S. at 581. Thus, in areas of truly local concern, States have discretion to decide how they will govern. Compare *Oregon v. Ashcroft*, *supra*, fn.20, with *Washington v. Glucksberg*, 521 U.S. 702 (1997) (upholding state's prohibition against assisted suicide).

The same is true in this case. If intrastate cultivation and possession of cannabis for personal medical use on the advice of a physician truly does not affect interstate commerce, then the question of how a State has chosen to regulate the issue should add little to the analysis. A State would be free to decide whether or not it wishes to permit the use of cannabis for medicinal purposes. If it wishes to address the issue in a different way, or indeed, does not recognize such use as legitimate, the State is quite capable of limiting or prohibiting such use and maintaining criminal and/or civil sanctions to enforce that limit or prohibition.[31] Accordingly, under the Court of Appeals' ruling, Congress would be unable to regulate the intrastate activity in question, **even** in States that have not approved the medicinal use of cannabis.

2. The Court of Appeals' Ruling Would Not be Limited to the Use of Cannabis.

The Court of Appeals ostensibly ruled only on the intrastate cultivation and possession of cannabis for personal medical use. However, the ruling would in theory apply to a wide variety of controlled substances. It would encompass any narcotic that could be cultivated locally, such as opium, ibogaine, or peyote. Indeed, it would apply to **any** controlled substance that could be produced with local materials, such as methamphetamine,

[31] In Maryland, for example, recent legislation merely requires a court to consider a defendant's use of cannabis for medical purposes as a mitigating factor in a criminal prosecution. If convicted, a defendant must pay a $100 fine.

heroin, and MDMA (ecstasy).[32] See Proposition 200, "The Drug Medicalization, Prevention, and Control Act of 1996," Title 13, ch.34, Ariz. Rev. Stat. sec.13-3412.01 (physician may prescribe any Schedule I substance). All these substances can be argued to have "medical" uses. Indeed, methamphetamine, cocaine (and coca), and opium are located in Schedule II of the CSA. Heroin is used medically in the UK.[33]

Furthermore, under the Court of Appeals' analysis, the use of such substances, or products made from them, would be exempt from federal regulation, even if the seeds or certain other components had traveled in interstate commerce. See *Raich v. Ashcroft*, 352 F.3d 1222, 1233 fn. 8 (9th Cir. 2003). See also, *U.S. v. McCoy*, 323 F.3d 1114,1125 (film and camera used to take pornographic photograph were manufactured out of state); *U.S. v. Stewart*, 348 F.3d 1132, 1135 (9th Cir. 2003)(parts for homemade machine gun had moved in interstate commerce).

Hence, the reach of the appellate court's ruling would permit the establishment of a wholly separate, quasi-medical system of "homemade" controlled substances. Surely this would subvert the FDA's and DEA's ability to regulate such products and thereby adversely affect interstate commerce in approved medical products.

In addition, it would wholly undermine the careful state and federal protections that have been enacted to protect patients who are the subjects of research involving investigational products, i.e., new drugs. Under the FDCA and CSA, physicians are permitted to conduct research with investigational products only if they have submitted adequate evidence of safety, obtained Institutional Review Board approval, and otherwise satisfied the requirements of the IND process. If the product contains a controlled substance, the physician must obtain a research registration (license) from the DEA; that registration is limited to the specific substance to be used, and the specific protocol to be followed, in the study. However, under the Court of Appeals' ruling, a physician could endlessly "research" unapproved products containing controlled substances without satisfying these

[32] Morphine can be easily produced from the opium poppy using chemicals lawfully available on the open market. Similarly, the conversion of morphine to heroin base is a relatively simple and inexpensive procedure. DEA Opium Report, *supra*, at 9-10.

[33] Indeed, heroin was originally manufactured for medical use, as a cough suppressant for patients with tuberculosis. DEA Opium Report, *supra*, at 2.

requirements. Patients might be used as unwitting guinea pigs—exactly the situation that the federal and state research regulations seek to avoid.

3. The Concept of "Noncommercial" Cultivation and Possession Would Allow Widespread Use Across a State.

The Court of Appeals attempted to limit its ruling to "noncommercial" cultivation and possession of cannabis for personal medical use. However, the ruling cannot be so easily contained. Indeed, the Court of Appeals' ruling avowedly encompassed the cultivation and distribution or delivery (albeit perhaps constructive in this case) of cannabis to a patient by third parties. Depending on the state law, a "caregiver" may be authorized to cultivate cannabis (or manufacture other controlled substances) for more than one patient. See Calif. Health & Safety Code sec. 11362.7(d). Furthermore, such cultivation/manufacture could arguably remain "noncommercial" even if the caregivers are compensated for their out-of-pocket expenses, or even for their services, **so long as they do not receive compensation for the cannabis itself**. See Calif. Health & Safety Code sec. 11362.765(c).

Furthermore, it is a small step from the situation presented here to one in which a "non-profit" dispensary provides cannabis (or some other controlled substance) to individuals for medical use. See *County of Santa Cruz v. Ashcroft*, 314 F.Supp. 1000 (N.D. Cal. 2004)(non-profit collective allowed under *Raich* to distribute cannabis). The Oakland Cannabis Buyers' Cooperative, whose distribution of cannabis was the subject of this Court's opinion in *U.S. v. OCBC*, 532 U.S. 483 (2001), has also argued that its distribution falls squarely within the Court of Appeals' ruling in this case. See *U.S. v. OCBC*, Nos. 02-16334, 02-16534, 02-16715, Appellants' Supplemental Brief (April 29, 2004).[34] Depending on the altruism of donors, such nonprofit collectives or cooperatives may be able to provide cannabis to members without charge. Thus, the court's ruling may have the effect of authorizing

[34] OCBC is organized as a Consumer Cooperative Corporation under Calif. Corp. Code sec. 12700 *et seq. Id.* Recent California legislation authorizes collective or cooperative cultivation of cannabis under the CCUA. Calif. Health & Safety Code sec. 11362.775.

numerous collectives or cooperatives to cultivate cannabis (and/or manufacture other controlled substances) within a State's borders.[35] Again, this would seriously disrupt the current federal regulatory system for medical products containing controlled substances.[36]

4. The Court of Appeals' Ruling Will Negatively Impact on the Development and Availability of Approved Medical Products.

As recognized by the dissent in the ruling below, the proliferation of such an underground system would negatively affect the incentives of pharmaceutical companies to expend resources on research and development programs involving cannabis or other controlled substances. For example, the Institute of Medicine (IOM), in its 1999 report *Marijuana as Medicine: Assessing the Science Base*, described the many financial and other obstacles that would impede the development of cannabis-based pharmaceutical products, even if a parallel, "informal" system did not exist. The Court of Appeals' ruling would increase these disincentives and potentially prevent the United States from responding to the IOM's call for the development of rapid-onset, alternative delivery systems for cannabis- or cannabinoid-based products.

The experiences of other countries clearly demonstrate that chaos erupts when a national regulatory system must compete with an informal system of local cannabis cultivation and use. In the Netherlands, cannabis is grown for medical use by two cultivators who are licensed by the government's Office of Medicinal Cannabis and whose cultivation practices must be standardized in conformity with Good Agricultural Practices. Even so, the cannabis has such high microbial content that it must be irradiated before it can be distributed to patients. Scholten, W., "Therapeutic Cannabis in the Netherlands," Drug Information Association Annual Meeting (June 17, 2004) (presentation). Furthermore, the government's efforts to produce high quality herbal cannabis have caused the price of that cannabis to exceed that of crude cannabis

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[35] In Oregon, an initiative has qualified for the November ballot that would allow non-profit dispensaries to distribute cannabis for medical use.

[36] This Court has **not** adopted a categorical rule against aggregating the effect of intrastate non-economic activity. *U.S. v. Morrison*, *supra*, at 613.

available in "coffee houses." Despite the uncertain quality of such unstandardized cannabis, patients are choosing to purchase it over the government's product, and the government's program is now in jeopardy. Scrip, *World Pharmaceutical News* (July 13, 2004). The impact of an informal cultivation system would be even greater on true pharmaceutical products that have been fully tested, standardized, refined, and are administered through medically-appropriate, nonsmoked delivery systems.

Canada, too, is facing the same dilemma. Forced by its courts to allow patients to use cannabis for medical purposes, Canada has funded and licensed a single cultivator to produce "medical quality" cannabis for direct distribution to patients (or through their physicians). However, patients dislike the governmental product and are urging the government to license the many small dispensaries that provide cannabis to patients outside the law. Beeby, D., "Canadian Pot Smokers Spurning New Batch of 'Stronger' Health Canada Marijuana," *The Canadian Press* (July 12, 2004).

5. California's "Medical Marijuana" System Has Placed Physicians in an Untenable Position and Could Ultimately Threaten to Obliterate the Distinction Between Medical and Non-Medical Use.

The Court of Appeals stressed that the patients' possession and use of cannabis did not affect interstate commerce, in part because they were acting on the advice of their physicians. However, it is difficult to understand why the mandated involvement of a physician should attenuate, rather than strengthen, the nexus between the activity in this case and interstate commerce. California--like other states--has authorized the use of cannabis for medical purposes, not simply by revoking its criminal laws as to patients diagnosed with certain medical conditions. Rather, it has utilized a "prescription medicine" model to identify when a patient's use of cannabis is "medical." That is, a patient can lawfully cultivate (or otherwise obtain), possess and use cannabis **only if** approved or recommended **by a physician**.

The State of California has placed physicians in an impossible position. On the one hand, the State has forced physicians into the role of legal gatekeepers of patients' lawful use and possession of cannabis. On the other, it has failed to provide them with objective scientific standards and data to use in

exercising that authority. In fact, the State has endowed physicians with tremendous, indeed, almost unfettered, power to undermine the effectiveness of the federal regulatory system--ironically, a system fervently supported by all major medical associations.

As indicated above, the standards of the medical profession are no longer local or provincial, but rather are evidence-based. While a physician must always use professional judgment, this judgment must be informed by the "best evidence" available, typically the results of controlled clinical trials conducted in the United States or elsewhere around the world. For example, in determining appropriate uses (on- or off-label) of an *approved* pharmaceutical product, physicians look to articles in national specialty peer-reviewed journals describing such trials and case studies presented at national conferences. Lyman, G., and Kuderer, N., "A Primer for Evaluating Clinical Trials," Moffitt Cancer Center, *Cancer Control* (Sept.-Oct. 1997).

California has given its physicians no assistance in this effort, and the Court of Appeals' decision will exacerbate this conundrum. The Court of Appeals appears to contemplate that the physician will somehow divine what type of use by patients qualifies as "medical." However, the CCUA does not provide guidance. While enumerating a number of specific conditions that are covered by the act, the Act also authorizes patients to use cannabis for "any other illness for which marijuana provides relief," as determined by their physicians. Calif. Health & Safety Code sec. 11362.5(b)(1)(A).

Although the patients in this case alleged that they had failed on all conventional medications, neither the Court of Appeals' ruling, nor state law (the CCUA), limits its reach to such patients. Indeed, under the Court of Appeals' ruling, patients could completely reject conventional medicine, in favor of "homegrown" concoctions containing controlled substances, and, if a physician were to approve it, would be beyond the reach of the FDCA and CSA. Again, this would permit a wholly separate underground "medical" system to exist for controlled substances and other pharmaceutical products.

The significance of this step cannot be underestimated. It would take us back to the days when the practice of medicine was based on intuitive judgment, rather than objective data, and patients could easily obtain medical products that were unstandardized, unproved and often unsafe. A State could even authorize a physician to conclude that, since opiate addiction is a

brain disease, opiate addicts should be allowed to "self-treat" with heroin or opium, and state law could permit such a "medical" use. However, Congress long ago determined that the federal government, rather than the medical profession or the States, would determine how, and under what circumstances, narcotics could be used to treat opiate addiction.

The mere fact that a physician has recommended to a patient that he/she use a controlled substance, and the fact that such substance can easily be manufactured or prepared locally by the patient or others, does not deprive Congress of its power to control the use of that substance. The federal government should not, of course, heartlessly institute a criminal prosecution against a suffering patient, but rather should seek to ensure that the patient can obtain proper medical care and treatment. However, this is a policy matter that can be dealt with through the political process. Congressional **power** to regulate such conduct does not disappear in the face of a physician's advice--whether or not State law has given that physician gatekeeping power.

CONCLUSION

The Treaty Power provides an independent source of congressional authority upon which the Controlled Substances Act should be upheld in this case. By enacting and enforcing the CSA, the United States has thus far served as an exemplar to the international community regarding compliance with the obligations of the Single Convention. The Court of Appeals' ruling, if allowed to stand, will subvert those efforts. In addition, the activities at issue here, if aggregated with similar activities around the country, will eviscerate the federal regulatory system governing medical products—a system resulting from a century of difficult choices and hard-won lessons. Congress can without question conclude that such an evisceration would substantially and adversely affect interstate commerce. For the foregoing reasons, *amici* urge this Court to reverse the Court of Appeals' ruling.

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JOHN D. ASHCROFT,
Attorney General, et al.,

Petitioners,

v.

ANGEL McCLARY RAICH, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

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INTEREST OF THE *AMICUS*

The Institute for Justice is a nonprofit, public interest law center committed to defending the essential foundations of a free society through securing greater protection for individual liberty and restoring constitutional limits on the power of government. Central to the mission of the Institute is guaranteeing that Congress be limited to its enumerated powers under Article I, Section Eight of the U.S. Constitution. The Institute is filing this brief in support of the Respondents. The parties in the case have consented to the filing of this *amicus* brief.[1]

SUMMARY OF ARGUMENT

The decision of the Ninth Circuit should be affirmed on both narrow and broad grounds. The narrow ground is that the government's assertion of federal power is inconsistent with the limitations on the Commerce Clause that *United States v. Lopez*, 514 U.S. 549 (1995) and *United States v. Morrison*, 529 U.S. 598 (2000) place on this Court's earlier decision in *Wickard v. Filburn*, 317 U.S. 111 (1942). The broad ground is that *Wickard v. Filburn*, on which the government relies, was wrongly decided and should be forthrightly overruled on the ground that it is wholly inconsistent with the original design of the federal system. *Wickard* read the commerce power to reach all economic and commercial transactions that had a substantial effect on interstate commerce. In so doing, it repudiated this Court's seminal decision in *Gibbons v. Ogden*, 22 U.S. 1 (1824), which held that the clause, broadly read, extended to all cross-border transactions, which included both the shipment of goods and services across state lines

[1] Counsel for the parties in this case did not author this brief in whole or in part. No person or entity, other than *amicus curiae* Institute for Justice, its members, and its counsel made a monetary contribution to the preparation and submission of this brief.

and the use of the various instrumentalities of interstate commerce to achieve that end.

Starting with the narrow ground, *Lopez* announced a return to first principles. 514 U.S. at 553. It therefore began with the incontrovertible proposition that the Constitution delegates to the Congress only enumerated powers. From that premise, this Court concluded that a simple Congressional say-so does not establish federal power. Rather, the subject matter of the legislation must fall within one of the enumerated powers. To show that particular legislation falls under the commerce power, therefore, Congress must offer some reasoned demonstration of a substantial effect on interstate commerce. As articulated in *Lopez* and *Morrison*, this Court now requires, at a minimum, some commercial or economic transaction to sustain federal power. Such a substantial effect has not been established in this case.

In addition, this case is wholly unlike *Wickard* in several key respects. In *Wickard* the defendant sought to act free from all restraints under either federal or state law. In this case, California's system of regulation limits access to marijuana and proscribes its diversion into the market for illicit drugs. But, in contrast to *Wickard,* California introduces a valid state police power interest by advancing the health and comfort of its citizens. In addition, in *Wickard*, a very large share of the overall grain market – perhaps as much as 20 percent – was used in home consumption. The key question of fact here, to which the government has devoted no attention, is the extent of leakage from the marijuana supplied under this program into commercial circulation. The proper approach would be to examine California's program as it is in fact administered. If California administers its program in ways that have a substantial effect on interstate commerce, the state should be able to reform its program to ensure that marijuana supplied under the program will go overwhelmingly to medically needy individuals within the state.

In contrast to the narrow approach, the outright rejection of *Wickard* would eliminate the difficult line-drawing determinations that *Lopez* and *Morrison* require. To be sure, *Lopez* confounded the common belief that after *Wickard* the principle of enumerated powers was a dead letter because every activity under the sun had some indirect effect on interstate commerce. But *Wickard* itself was not faithful to the original understanding of the Commerce Clause, or to the seminal case of *Gibbons v. Ogden,* 22 U.S. 1 (1824) (cited in *Lopez,* 514 U.S. at 553), which only stands for the proposition that navigation across state lines is covered by the interstate commerce power. *Id.* at 203. Nothing in the original Constitution indicates that local manufacture, mining, or agriculture falls within the scope of the power.

The ordinary doctrine of changed conditions, whereby traditional doctrine is adapted to new and unforeseen circumstances, makes it imperative that the commerce power apply to interstate transport and communication by rail, plane, or wire. That principle does not require that the domain of local commerce be shrunk to nonexistence. The Commerce Clause gave the federal government *no* power over purely *intra*state transactions, and no account of national economic interdependence required that the Court bestow that power on Congress in 1942 or preserve it today. Overruling *Wickard* will do nothing to stop the federal government from attacking the interstate trafficking in drugs. The states can take over where the federal government leaves off on matters of purely local distribution and use, adopting those policies that they think appropriate to deal with the problem, including compassionate use provisions.

The return of the commerce power to its original contours will *improve* the economic welfare of the United States by allowing for state competition in the regulation of economic affairs and state experimentation in dealing with difficult issues of drug use. Congress retains all power to prevent state bottlenecks and blockades of

economic activity. The return to the original meaning of the Constitution is as imperative today as it ever was. *Lopez* undercut the intellectual foundations of *Wickard*. This Court should now finish the job by overruling *Wickard*.

ARGUMENT

I. The Medical Use of Marijuana under the California Compassionate Use Act Bears No Substantial Relation to Interstate Commerce.

A. This Court's Decision in *United States v. Lopez* Reaffirms the Doctrine of Enumerated Powers.

In *Lopez*, this Court announced a tripartite test to determine the scope of Congress' power to regulate under the Commerce Clause.

> First, Congress may regulate the use of the channels of interstate commerce. Second, Congress is empowered to regulate and protect the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities. Finally, Congress' commerce authority includes the power to regulate those activities having a substantial relation to interstate commerce, i.e., those activities that substantially affect interstate commerce.

Lopez, 514 U.S. at 558-59 (citations and internal quotations omitted).

The first two heads of Congressional power, which have engendered little or no controversy, are manifestly insufficient to sustain the use of federal power to prevent the local consumption of marijuana for any purpose. As this Court has noted, all the pressure is on the third category that *Wickard* creates – that of substantial effect on interstate commerce. The challenge that the government

faces in this case is to read that category broadly enough to cover California's medical marijuana program without obliterating the doctrine of enumerated powers that *Lopez* reaffirms.

In the years between *Wickard* and *Lopez*, it was commonly assumed that Congress could bring any and all regulation into that third category. But in *Lopez*, this Court confounded that view by limiting the *Wickard* substantial effects test. The Court did so by analogizing it to the *Shreveport Rate Cases*, 234 U.S. 342 (1914), which upheld the power of the Interstate Commerce Commission to regulate the rates of a purely intrastate railroad that was in direct competition with an interstate railroad. The *Shreveport* court upheld the regulation because if Congress could not regulate the rates of the intrastate railroad, it would undermine the federal regulation of interstate railroads. 234 U.S. at 350-51. Yet it is critical to understand the limitations of that decision. The *Shreveport Rate Cases* applied *only* to instrumentalities of interstate commerce, that is, to those involving transportation and communication. 234 U.S. at 352. Employing the exact same analysis, the *Lopez* court explained that the creation of a gun-free school district was not a situation "in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561. After *Lopez*, *Wickard* is best understood as an extension of the *Shreveport* rule on competitive interdependence between local and national markets to manufacturing, agriculture, mining, and other local productive activities. Hence, to the extent that local production competes with products that move in interstate commerce and thereby has a substantial effect on the price and quantity of goods shipped in interstate commerce, *Wickard* subjects them to Congressional legislation.

Wickard itself explained that the local consumption of home-grown wheat substantially affected interstate commerce because it constituted at least 20% of the

national grain market. Exempting that wheat from federal price and production controls would, like the intrastate railroad in *Shreveport*, significantly undermine Congressional attempts to regulate the price of interstate wheat. *United States v. Wrightwood Dairy Co.*, 315 U.S. 110 (1942), decided only a few months prior to *Wickard*, held that the Commerce Clause allowed the regulation of milk sales that directly competed with and substantially affected interstate milk sales. *See id.* at 117-18 (intrastate milk constituted 60% of Illinois market). *Wickard* went one step further, applying the *Shreveport* principle to internal consumption as well as sales, but it still required direct competition and a substantial effect on interstate commerce.

B. The Congressional Findings in Support of the Controlled Substances Act Do Not Justify the Application of the Act to the Conduct in This Case.

Now that *Lopez* has affirmed the requirement of an actual substantial effect on interstate commerce, the question then arises whether Congress has established that nexus between California's compassionate use program and interstate commerce. In principle that turns, after *Wickard*, on the degree of separation and connection between drug trafficking and medical use of marijuana. Here, as an empirical matter, much depends on the operation of California's program. If that program effectively allowed all individuals to obtain marijuana for recreational use, this case would be more difficult to distinguish under *Wickard*. The lax administration of the program could support a credible claim that the California statute legalized all marijuana use, effectively ending any separation between the medical and recreational markets.

The brief submitted by a group of Congressional Representatives, citing to reports in the media, purports to

show that just this mixing of markets has happened with the administration of the program in Oakland, California, and perhaps other areas. U.S. Rep. Brief at 18-23. There are two problems with the Representatives' claims. First, none of the information they cite is part of the record in this case. Any consideration of those factual assertions would have to occur on remand, where such evidence could be tested. Second, and most critically, the government has chosen not to engage in any such close empirical investigation of the operation of the California program. It disavows any need for an actual, factual connection between the medical marijuana program and interstate commerce, and, instead, mounts a *facial* attack on any and all state programs that allow for the medical use of marijuana, regardless of how they are administered. The Petitioners consciously exclude any possibility that such a program could be put into place by any state without the blessing of the United States government. In so doing, they rely on a set of 1970 findings that cover two points: first that all use of marijuana is necessarily harmful, and second that it is impossible to keep the medical market separate from the recreational market. Some comments on both points seem appropriate.

First, medical use: The government points to the findings of the CSA that state there is no medical use for marijuana in order to establish a federal interest sufficient to bolster its claim under the commerce clause. The brief submitted by interested members of the House of Representatives relies on various sources to defend the related claim that "botanical marijuana" has never been able to pass the "strict scientific standards" for drug approval because "marijuana is fundamentally bad for human health" insofar as it is responsible for a list of harmful human effects including "brain damage, lung damage, and heart disease." *See* U.S. Rep. Brief at 13-14, citing sources. For the purposes of this argument, we assume that these

claims about the harmful effects of marijuana are true for the general population.

However, these general findings, if relevant to the Commerce Clause issue at all, hardly support a *universal* ban that would make it unnecessary to investigate the operation of the California program. Respondents Raich and Monson are not part of the general population blessed with good health. They are at present in constant pain and face diminished life prospects no matter what they do. Accordingly, it is quite rational for them to take marijuana, despite its adverse side effects, just as they would take approved forms of other medicines or treatments known to have potent adverse side effects. The key question in all cases is whether the substance used has more beneficial effects than harmful effects, which, contrary to the unsupported findings in the CSA, can only be decided on an individual basis for people who suffer from various maladies. No healthy person would undergo surgery or chemotherapy, which are well known to cause all sorts of heinous tissue damage. But for a person with cancer, either or both these courses of action make perfect sense. The entire system of medical treatment in the United States rests on the principle of individual self-determination. *See Schloendorff v. Society of the New York Hospital*, 211 N.Y. 125, 129-30 (1914). The truly frightening import of the government's position on drugs lies in its determination to prohibit recreational use by sacrificing traditional respect for individual autonomy.

Petitioners and their *amici* rely on selective citations to support their claims about the dangers of medical uses of marijuana. For example, these briefs nowhere cite or discuss the Institute of Medicine study, *Marijuana and Medicine* (Joy, Watson and Benson 1999), which recommends the development of drug delivery systems for "cannabinoid drugs" and explicitly recognizes that patients should be allowed to smoke marijuana if they are unable to obtain relief from approved drugs. *See also*, Richard E.

Musty & Rita Rossi, *Effects of Smoked Cannabis and Oral Δ^9-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials*, 1 J. Cannabis Therapeutics 29 (2001), which concluded that "it appears that smoked marijuana can be a very successful treatment for nausea and vomiting following cancer chemotherapy." In light of this evidence, unquestioning deference to the findings of the CSA as to the lack of medical value of marijuana is wholly unwarranted.

Second, market interdependence: The separation between legal and illegal uses should be treated as a matter of fact, not as a universal truth. If that separation is largely maintained in practice, then it is possible to accommodate both the federal policy against recreational drug use and the exception to federal power for the medical use of medical marijuana when affirmatively adopted under state law. The key point is that neither the CSA in 1970, nor the sparse record before this Court today, provide any evidence about either the universal dangers of marijuana or the necessary interdependence between a specialized local market and the general trafficking of marijuana. *See* 21 U.S.C. §§ 801 (2)-(6) (providing only general findings). The government's effort to show that the CSA necessarily and in all cases falls within the scope of the commerce clause represents a leap of faith that this Court should not accept. As the Ninth Circuit correctly noted below, that determination in the abstract is not decisive in the context of this litigation, for even though the CSA has been upheld under *Lopez* as applied to the general distribution of drugs, the particular context matters. *See, e.g., United States v. Visman,* 919 F.2d 1390, 1393 (9th Cir. 1990); *Proyect v. United States*, 101 F.3d 11, 13 (2d Cir. 1996). That result follows directly from the treatment of Congressional findings outlined in *Lopez*. Although there is some dispute as to exactly how much weight should be attached to these findings, *Lopez* makes

clear that they should in no circumstances be regarded as conclusive:

> Although as part of our independent evaluation of constitutionality under the Commerce Clause we of course consider legislative findings, and indeed even congressional committee findings, regarding effect on interstate commerce, the Government concedes that "neither the statute nor its legislative history contain[s] express congressional findings regarding the effects upon interstate commerce of gun possession in a school zone."

Lopez, 514 U.S. at 562 (citations omitted).

That observation is especially pertinent here because the general findings about the dangers of marijuana to "the health and general welfare of the American people" make no specific findings about the effect of marijuana on seriously ill patients. Likewise, the general findings on the contributions that local distribution and possession make to the overall markets are made without any reference to the statutory controls put in place by California's compassionate use statute or any similar program. These omissions are not trivial in light of *Lopez*, which struck down the Gun-Free School Zones Act in part because the legislation "contains no jurisdictional element which would ensure, *through case-by-case inquiry*, that the firearm possession in question affects interstate commerce." *Lopez*, 514 U.S. at 561 (emphasis added).

C. The Findings Below Do Not Meet the Reinvigorated Rational Basis Test Applied in *Lopez*.

In order to hide from these serious deficiencies in the record, the Petitioners and their *amici* stress that *Lopez* did not change the lay of the constitutional landscape because it continued to adhere to the rational basis test used in earlier cases, which supposedly obviates the need

for any such demonstration. (*See, e.g.*, Petitioners' Brief at 16-17.) But once again, this isolated reference to the rational basis test misses the sea change that *Lopez* brought about. Before *Lopez*, the phrase "rational basis" could have been read as tantamount to the necessary inference that the Commerce Clause reached any challenged legislation; after all, no statute was struck down on Commerce Clause grounds between *Wickard* and *Lopez*. But *Lopez did* invalidate a statute on Commerce Clause grounds, and in doing so, it confirmed that "rational basis" does not mean the blind, unquestioning deference advocated by Petitioners. Thus, Chief Justice Rehnquist wrote: "Since that time [of *Wickard*], the Court has heeded that warning and undertaken to decide whether a rational basis existed for concluding that a regulated activity sufficiently affected interstate commerce." *Lopez*, 514 U.S. at 557. Lest anyone mistake the clear implication that the revived rational basis test has some teeth, Justice Rehnquist added a footnote citing *Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc.*, 452 U.S. 264 (1981), for the proposition that "simply because Congress may conclude that a particular activity substantially affects interstate commerce does not necessarily make it so." *Id.* at 311 (Rehnquist, J., concurring). In this new rational basis regime, congressional findings need not carry the day simply because they ape the language of *Wickard*, especially when drafted without reference to the particular context in which the application of the statute is challenged.

D. The "Necessary and Proper" Clause Does Not Extend the Scope of the Commerce Power.

Petitioner cannot suppress the revival of Commerce Clause jurisprudence by unexplained reference to the Necessary and Proper Clause, U.S. Const. art. I, § 8, cl. 18, which states that Congress shall have the Power "to make all Laws which shall be necessary and proper for carrying into Execution

the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof." *Id.* To be sure, this clause received a broad construction in *McCulloch v. Maryland*, 17 U.S. 316, 421 (1819), where Chief Justice Marshall collapsed the two distinct terms "necessary" and "proper" into the single weaker word, "appropriate," a construction that this Court recently applied in connection with the Spending Power in *Sabri v. United States*, 124 S. Ct. 1941, 1949-50 (2004), as a means to preserve and protect the vast sums of federal money that are distributed daily through the nation's banking system. But even this broad interpretation does not support the Petitioner's implicit assertion that this clause extends the ultimate reach of the Commerce Clause. As Madison explained, the entire purpose of the Necessary and Proper Clause was to give Congress the *means* to achieve its stated and enumerated ends. There is "[n]o axiom in law, or in reason, that whenever the end is required, the means are authorized." *The Federalist* No. 44, at 285 (James Madison) (Clinton Rossiter ed., 1961). The Necessary and Proper Clause therefore does *nothing* to expand the scope of the Commerce Clause or to compromise the principle of enumerated powers.

Just that conclusion was reached by Chief Justice Marshall in *Gibbons v. Ogden*, 22 U.S. 1 (1824), some five years after his opinion in *McCulloch*, where in offering his account of the commerce power as covering navigation and other cross-border transactions, he disdained any reliance on the Necessary and Proper Clause. In approaching this question, Marshall first rejected the claim that this Court should adopt a "strict construction" of the commerce clause when that view would render the Constitution ineffectual for achieving its great purpose of forging a nation out of a collection of states. Then in speaking of the Necessary and Proper Clause, Marshall wrote:

> In the last of the enumerated powers, that which grants, expressly, the means for carrying all others into execution, Congress is authorized "to make all laws which shall be necessary and proper" for the purpose. But this limitation on the means which may be used, is not extended to the powers which are conferred; nor is there one sentence in the constitution, which has been pointed out by the gentlemen of the bar, or which we have been able to discern, that prescribes this rule.

22 U.S. at 187-88. *Gibbons* contains no citation to *McCulloch* because Chief Justice Marshall thought that the Necessary and Proper Clause only places a limitation on the means to achieve an enumerated power, but does not limit the power in question. By the same token, his refusal to rely on the Necessary and Proper Clause shows he thought that it also does nothing to *expand* any enumerated power. It is just inapplicable to the choice of ends. Thus, the clause would allow Congress to avail itself of whatever appropriate tools it needed to stop activities that fall within interstate commerce. But if "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law," *Raich v. Ashcroft*, 352 F.3d 1222, 1228 (9th Cir. 2003) is an activity that falls outside the scope of the Commerce Clause, the Necessary and Proper Clause does not bring it back in.

E. Enforcing the Limited Scope of the Commerce Clause Will Advance the Functional Objective of Making the States Laboratories for Experimentation on Social Matters.

Finally, the arguments here are not solely textual in nature, but are also structural and functional: the Ninth Circuit's interpretation of *Lopez* is consistent with the broader principles of dual sovereignty so critical to the success of our basic federalist constitutional scheme. One fundamental virtue of federalism is that it allows for experimentation at the state level in the solution of difficult issues that divide a nation. That proposition was

made famous in Justice Brandeis's dissent in *New State Ice Co. v. Liebman*, 285 U.S. 262 (1932), where he wrote: "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."

This case deals with questions that every government must face in the regulation of the conduct of its citizens, specifically in this instance a state regime that allows for personal choice on matters of life and death. In this context, the local interest in experimentation is strong enough to prevent one monolith from imposing a uniform nationwide policy that precludes across the nation all compassionate use of marijuana for medical purposes. As of this writing, Arizona, Alaska, Colorado, Maine, Maryland, Oregon, Vermont, and the District of Columbia have adopted programs similar to California's. Other states have adopted alternative policies for dealing with medical marijuana, including decreasing the fines for medical use or making medical necessity a legitimate defense to prosecution. *See* Respondents' Brief at 2. In trying several different approaches, these states are exemplifying the role of states as laboratories where varying strategies may be tried and evaluated. Nothing in the Commerce Clause gives the United States the power to veto those experiments.

II. This Court Should Overrule *Wickard v. Filburn* and Return the Commerce Clause to the Proper Construction It Received in *Gibbons v. Ogden* and *United States v. E.C. Knight*.

A. The Local Manufacture and Local Consumption of Any Product, Including Marijuana, Are Matters Outside the Proper Scope of the Commerce Power.

The problems inherent in modern Commerce Clause jurisprudence go deeper than the line-drawing problems inherent in Wickard. The scope of federal power can be

rationalized only by taking the simple but critical step of returning Commerce Clause jurisprudence to its settled limits prior to the New Deal developments that culminated in the *Wickard* decision. *See Lopez*, 514 U.S. at 584-602 (Thomas, J., concurring) (describing doctrinal drift in Commerce Clause jurisprudence and suggesting reconsideration of substantial effects test).

Although it is not necessary for the resolution in this case, *amici* respectfully urge that *Wickard* be forthrightly overruled. The case is flatly inconsistent with every major approach to constitutional interpretation, whether it stresses the text of the Commerce Clause, the basic constitutional structure, the pre-1937 precedents on the matter, or the functional justifications for the rule. *Wickard* was adopted in an era when conventional wisdom held that major problems of social dislocation required federal solutions regardless of constitutional constraints. In its brief, the government delicately states that *Wickard* allows the government, to regulate "the supply, demand, and prices in the interstate wheat market." *See* Petitioner's Brief at 15. In plain English, it wanted to expand the scope of the commerce power to rig prices as part of a comprehensive federally-sponsored agricultural cartel in an otherwise competitive market. For the following reasons, that should never have been allowed to happen.

B. The Substantial Effects Test Does Not Allow Congress to Regulate Agriculture and Manufacturing under the Commerce Clause.

1. The Text of the Commerce Clause Does Not Support the Broad Reading of the Substantial Effects Test Found in *Wickard*.

To start with the textual issue, it is useful to restate the Commerce Clause in full: "Congress shall have the

power . . . To Regulate Commerce with foreign Nations, and among the several States, and with the Indian tribes." U.S. Const. art. I, § 8, cl. 3. Looking at it first in isolation from the rest of the Constitution, the term "commerce" has to have a meaning that is consistent across all three heads of the clause. This canon of construction was explicitly adopted by Chief Justice Marshall in explaining why the power of Congress to regulate commerce among the several states included the power to regulate navigation. He first explained that foreign commerce included the power to regulate navigation. *Gibbons,* 22 U.S. at 189-94. He then continued: "If this be the admitted meaning of the word, in its application to foreign nations, it must carry the same meaning throughout the sentence, and remain a unit, unless there be some plain intelligible cause which alters it." *Id.* at 194.

The same principle that explains why interstate commerce must comprehend navigation among states explains why it cannot be read to embrace ordinary local activities of farming and manufacture. As a matter of textual construction, it will not do to have one definition of "commerce" for foreign commerce, another for commerce among the states, and perhaps a third for commerce with the Indian tribes. As a textual matter, it is impossible to claim that, under the foreign commerce clause, Congress has the power "to regulate agriculture and manufacturing *within* foreign nations," even if those activities have a substantial effect on overall world prices. "With" and "within" have contradictory, not complementary meanings. The point here is *not* that the substantial effects test has no place in interpreting the commerce clause. Rather, it is that the same restricted meaning of the substantial effects test used in foreign commerce has to apply to federal efforts to regulate activities that are wholly internal within the states, even if their price effects are felt on interstate commerce. Commerce among the several states

does not mean agriculture and manufacturing within each state.

The sensible, narrower interpretation of the Clause (which is by no means narrow) necessarily includes, of course, all forms of cross-border transactions. It allows Congress to regulate all forms of transportation and communication that operate across state lines, as well as transactions for the provision of goods and services that take place in more states than one. *See, e.g., The Pipeline Cases*, 234 U.S. 548 (1914). More specifically, the natural reading of the Clause in no way compromises the ability of Congress to interdict cross-border transactions in the drug trade from outside the United States or among the several states. Yet, if under *Wickard*, "commerce" includes local production and consumption, then Congress has that power over foreign as well as interstate commerce. Logically, it follows that Congress should, under the Foreign Commerce Clause, have the power to regulate the production and consumption of grain anywhere in the world on the ground that these too influence the price and quantity of grain that can be exported from the United States. But, no one reads the Constitution as a charter for world domination.

The challenge, therefore, is to find a way to read the substantial effects test in ways that do not wholly obliterate the doctrine of enumerated powers. Once again the foreign commerce cases provide the key clue for, in this context, the test has been confined to the enforcement of antitrust laws for sales by foreign firms in transactions intended for the American market. Thus, in *Hartford Fire Ins. Co. v. California*, 509 U.S. 764 (1993), this Court was faced with an antitrust case that challenged certain contract provisions that insurers in the London market wanted to insert in its reinsurance policies sold in the United States. This Court wrote that "it is well established by now that the Sherman Act applies to foreign conduct that was meant to produce and did in fact produce some

substantial effect in the United States." *Id.* at 796. The words "substantial effect" in this sentence do *not* bear the same meaning that they have in *Wickard*, for it would be bizarre to claim that the substantial effects test that this Court adopted in *Hartford Fire* would allow Congress to regulate the home consumption of wheat in the English market because of its influence on world prices.

The key to understanding *Hartford Fire* lies in recognizing that this Court only adopted the same *restricted* meaning of the "substantial effects" test that informed the pre-1937 decisions that applied the antitrust laws to domestic business activities. Thus *Addyston Pipe & Steel Co. v. United States*, 175 U.S. 211, 238-40 (1899) upheld the application of the Sherman Act to the formation of a price-fixing cartel among iron pipe manufacturers. It requires no stretch of judicial imagination to assume that a cartel whose sole function is to rig the prices that sellers located in different states charge for their wares throughout the United States counts as part of "commerce among the several states." The same is true of *Swift & Co. v. United States,* 196 U.S. 375 (1905), which used the antitrust laws to attack a cartel among meat dealers that fixed the price for meat sold at the stockyards while the cattle in question were still moving within the stream of interstate commerce. Neither of these cases questioned the distinction between manufacture that is internal to the state and commerce among the several states that was announced, but misapplied, in *United States v. E.C. Knight Co.*, 156 U.S. 1, 14-15 (1895). *See* Richard A. Epstein, *The Proper Scope of the Commerce Power*, 73 Va. L. Rev. 1387 (1987).

These decisions are consistent with the judgment in *Hartford Fire* that allows the foreign commerce clause to reach transactions done with a view to committing antitrust violations in the American market, but not to routine business transactions between English insurers and their English clients. *Addyston Pipe* and *Swift* did not commit this Court to *Wickard* before 1937, just as *Hartford Fire*

does commit this Court to *Wickard* today. For the same limiting construction, see also The Foreign Trade Antitrust Improvements Act of 1982, 15 U.S.C. § 6a (2004), as construed in *F. Hoffman-LaRoche Ltd. v. Empagran S.A.*, 124 S. Ct. 2359, 2363 (2004). This reading of the commerce clause to the antitrust laws, either domestic or foreign, was not addressed by Chief Justice Marshall in *Gibbons*. But, this extension of the clause to antitrust actions, designed to preserve a competitive national market, was well established before *Wickard* and can be completely accepted without rejecting *Knight's* basic distinction between agriculture and commerce. After all, *Wickard* involved no contract or combination among local farmers.

2. The Pre-*Wickard* Construction of the Commerce Clause is Consistent with the Structure of the Constitution as a Whole.

The grammatical structure of the Commerce Clause is wholly consistent with the original recipe for the formation of our national union. Indeed, the recognition that differences in local policy, most critically on questions of slavery, was one major driver behind the doctrine of enumerated powers. Before the Civil War, everyone, North and South, understood that the Commerce Clause did not allow the abolition of slavery within the states by federal legislation. It is inconceivable that we suffered through a bloody Civil War if Congress could have, by simple legislation, abolished slavery in the United States because the practice, taken as a whole, has a profound influence on the quantity and price of goods that traveled across state lines. Instead, a wholly different reading of the issue is evident in Article I, Section 9, Clause 1: "The Migration and Importation of such Persons as any of the States now existing shall think proper to admit, shall not be prohibited by the Congress prior to the Year [1808]," U.S. Const. art. I, § 9, cl. 1. This oblique reference to the slave trade disabled Congress only from dealing with cross-national transactions. The only

reason why the abolition of the practice of slavery within any state was not likewise curtailed was that everyone on all sides knew that Congress had no power to regulate local agriculture or manufacture in the first place. The Commerce Clause did not allow Congress to abolish slavery within the states, which is why the Thirteenth and Fourteenth Amendments were necessary. The abolition of slavery had many fortunate consequences, but one of these was not an implicit expansion of the scope of the commerce power.

Similarly, the Eighteenth Amendment was passed as a constitutional amendment, not a federal statute. Prior case law made it clear that the states had the exclusive power to regulate the production and consumption of alcohol within their borders, while the federal government had the power to regulate the movement of alcohol between the states. *See, e.g., Kidd v. Pearson*, 128 U.S. 1, 20 (1888) ("No distinction is more popular to the common mind, or more clearly expressed in the economic and political literature, than that between manufacture and commerce"); *compare with Leisy v. Hardin*, 135 U.S. 100 (1890) (invalidating an Iowa statute that forbade the importation of intoxicating beverages into the state). Had Congressional power extended to local manufacture and consumption of alcohol, which undoubtedly had a substantial effect on the interstate market for alcohol, prohibition could have been brought about by simple Congressional legislation.

The basic conclusion that the Commerce Clause did not include local agriculture and manufacturing is reinforced by setting the Commerce Clause in its larger textual context. Article I, Section 8 contains an enumeration of specific powers granted to Congress. Each provision of our Constitution is presumed to have independent meaning. Yet *Wickard's* reading of the Commerce Clause is so broad that it makes redundant the grants of power found elsewhere within the same section. Surely the

taxation of all activities has some influence on interstate commerce, so that the power to tax granted under Article I, Section 8, Clause 1, would be redundant. Worse still, any limitations on the power to tax contained in that clause – the specific purposes for which taxes could be levied, and the uniformity requirement for "all Duties, Imposts, and Excises" – could be easily circumvented by running legislation through the Commerce Clause. Likewise, there would be no need for separate authorization of the power to pass uniform laws of bankruptcy under Article I, Section 8, Clause 4; nor any reason to respect the requirement that such rules be "uniform" across the United States. Finally, the creation of all forms of intellectual property clearly affects interstate commerce. Thus, the clause governing patents and copyrights in Article I, Section 8, Clause 8, turns out to be wholly anomalous if *Wickard* offers an accurate reading of the Commerce Clause. There is no reason why copyrights and patents need be issued only for limited terms, and confined only to writings and inventions. For discussion of just this possibility, see Thomas B. Nachbar, *Intellectual Property and Constitutional Norms*, 104 Colum. L. Rev. 272 (2004). None of these anomalies so much as arise if the substantial effects test is read in the narrow fashion of *Addyston, Swift, Hartford Fire.*

The *Wickard* view of the Clause also gives "commerce" a reading that is inconsistent with the use of that same term elsewhere in the Constitution. Thus Article IV, Section 9, Clause 6 provides that "No Preference shall be given by any Regulation of Commerce or Revenue to the Ports of one State over those of another." The point of this clause is to prevent each state from favoring its own traders on matters pertaining to either taxation or regulation. Here the phrase "regulation of commerce" is used in opposition to the regulation of revenue, and confined as such to navigation and trade. Substitute the phrase

"manufacture or agriculture" for "commerce" (as *Wickard* does) and the clause is devoid of all sense.

C. *Gibbons v. Ogden* Is Flatly Inconsistent with the Subsequent Extension of the Commerce Clause in *Wickard v. Filburn.*

Virtually all of these arguments from textual structure can be found in various portions of Chief Justice Marshall's opinion in *Gibbons v. Ogden, supra*, as well as Justice Thomas's concurrence in *Lopez*. For an accurate and careful dissection of the *Gibbons* decision, see David P. Currie, *The Constitution in the Supreme Court: The First Hundred Years 1789-1888* 168-176 (1985). Currie observes: "It bears emphasizing that in *Gibbons,* as in *McCulloch v. Maryland,* the great exponent of national power expressly acknowledges significant limitations on the reach of federal legislation; it was Marshall's successors who were to expand the commerce power to cover virtually everything." *Id.* at 170 (footnotes omitted). Chief Justice Marshall wrote with great eloquence about the need to avoid the canon of strict construction if its application would paralyze the operation of a great nation. His broad construction played a vital role in the preservation of Union and was resisted at the time by many who argued for a continuation of slavery under the banner of states' rights. But Marshall's meaning must be understood in light of the particulars of the controversy before him, which was whether New York could bar a ferry that wanted to cross into its waters from Elizabethtown, New Jersey by conferring an exclusive license of steamboats in New York waters on one person, Robert Livingston, of whom Ogden was an assignee.

In arguing that the Commerce Clause should receive a broader interpretation, Marshall's target was the cramped reading of the clause in *Livingston v. Van Ingen*, 9 Johns. 507 (N.Y. 1812), which limited the commerce power to

regulating transactions literally at the border between two states, and little more. Marshall also rejected Ogden's argument that the clause covered only buying and selling, but excluded the regulation of navigation. *Gibbons,* 22 U.S. at 189. Marshall's broader definition of commerce as "commercial intercourse" in dealing with foreign nations thus has to have the same meaning in connection with commerce among the states, in the absence of any marker to indicate that some different meaning was intended. *Gibbons*, 22 U.S. at 193-94. Marshall's entire discussion of the regulation of navigation and embargos made clear that the Union could be preserved only if Congress could regulate the navigation for the entire length of an interstate journey, from the depths of one state into the heart of another.

The modern efforts to justify *Wickard* have disregarded all these important qualifications. Thus Professor Tribe writes of the decision that while

> [t]he actual *holding* of *Gibbons* was a narrow one . . . Marshall indicated that, in his view, congressional power to regulate "commercial intercourse" extended to all commercial activity having any interstate component or impact – however indirect. Acting under the Commerce Clause, Congress could legislate with respect to all "commerce which concerns more states than one."

Lawrence Tribe, *American Constitutional Law* 808 (3rd ed. 2000). This short summary is packed with major errors.

First, Marshall is at great pains to make clear (as Tribe nowhere mentions) that inspection and quarantine and health laws are not part of interstate commerce, even though they "may have a remote and considerable influence on commerce," *Gibbons,* 22 U.S. at 203. Marshall's conception and examples are consistent with the view that interstate commerce covers the interstate journey and not what precedes or follows it, which is the exact opposite of what Tribe reports. Indeed it took an explicit decision of

this Court to hold that intrastate legs of an interstate journey are subject to federal regulation. *See The Daniel Ball*, 77 U.S. 557 (1871). Similarly, Marshall did not write that Congress "could legislate *with respect to all* 'commerce that concerns more states than one.'" Rather, his full sentence says precisely the opposite: "Comprehensive as the word 'among' is, it may very properly be *restricted* to *that* commerce which concerns more States than one," which for Marshall excluded "the completely interior traffic of a State." *Gibbons*, 22 U.S. at 194 (emphasis added). Additionally, Marshall said: "It is not intended to say that these words comprehend that commerce, which is completely internal, which is carried on between man and man in a State, or between different parts of the same State, and which does not extend to or affect other States. Such a power would be inconvenient, and is certainly unnecessary." *Id.*

Marshall's full sentences convey the meaning that some commerce (i.e., trade and intercourse) is outside the scope of the federal power because it is internal to the state. Marshall does not use the term, "commerce," as a synonym for all productive activity: there is no hint in *Gibbons* that any manufacture or agriculture fell within its scope. Indeed the word "agriculture" appears nowhere in Marshall's opinion, and the word "manufactures" appears but once, in a sentence that refers to "vessels carrying manufactures," which only reinforces the link between commerce and navigation. *Gibbons,* 22 U.S. at 216.

Nor is the *Wickard* interpretation advanced by noting that Marshall spoke of the "plenary" nature of the Commerce Power. His full proposition reads: "the sovereignty of Congress, *though limited to specified objects*, is plenary as to those objects, the power over commerce with foreign nations, and among the several States, is vested in Congress as absolutely as it would be in a single government, having in its constitution the same restrictions on the exercise of the power as are found in the constitution of

the United States." *Gibbons*, 22 U.S. at 197 (emphasis added). The italicized phrase respects the doctrine of enumerated powers.

D. The Interpretation of the Commerce Clause in *Gibbons* Offers a Far More Accurate Reflection of the Economic Realities of a Complex National Economy Than Does the Mistaken Reading in *Wickard.*

The reading that Marshall gave the Commerce Clause was suitable for the economy in the nineteenth century and is equally suitable for today. Whether the inquiry focuses on 1787 or 2004, the essential task of constitutional interpretation was to fashion a workable account of the commerce clause that preserves, over time, the same distribution of federal and state power. If the activities of the nation are more integrated today than in 1787, then there will be more transportation and communication across state lines, so that the federal government will exert control over a larger fraction of the economy today than it did 225 years ago *even when the definition of commerce among the several states is left unchanged.* The defenders of the well-nigh infinite reach of the commerce power have not carried their burden of explaining which changed social and economic circumstances compel any judicial acceptance of the *Wickard* version of the substantial effects test.

The strength of this position is made clear by a consideration of the various attacks that have been leveled on the pre-*Wickard* synthesis of the Commerce Clause. Thus, many defenders of *Wickard* claim that decisions like *E.C. Knight* retreated from *Gibbons* by resorting to a "formal" test in lieu of the "empirical" test ostensibly suggested in *Gibbons.* Tribe, at 811-12. *See also* Geoffrey R. Stone, Louis Seidman, Cass Sunstein & Mark Tushnet, *Constitutional Law* 181-82 (4th ed. 2001) (contrasting "formalism"

and "realism"). But those words are devoid of content. Marshall's concern was to delineate the respective spheres of control for different layers of government within a federal system. He knew that this distinctive structure could not find any area for state autonomy if all "remote" factors that had a "considerable" impact on commerce were subject to federal regulation. *Gibbons*, 22 U.S. at 193 (noting that inspection laws precede or follow commerce and thus are a state function). The subsequent cases that followed his injunction were similarly aware of the same structural limitations, to which they rightly responded, for example, by seeking out ways to define the appropriate limits of an interstate journey. *See, e.g., The Daniel Ball*, 77 U.S. 557 (1871), (allowing for federal licensing of intrastate ships whose goods flowed in interstate commerce). Before 1937, the major erosion of the Marshallian model arose with respect to communication and transportation that took place within a single state. Over time these entire networks were brought within federal power. *See, e.g., Second Employers' Liab. Cases,* 222 U.S. 20 (1911) (upholding a revised version of the Federal Employer Liability Act that treated intrastate commerce integrated with interstate commerce as subject to coverage under the Act); *Railroad Commission of Wisconsin v. Chicago, Burlington & Quincy,* 257 U.S. 563 (1923) (upholding the Transportation Act of 1920, 41 Stat. 456). Yet insofar as these cases only applied to transportation and communication, they were and remain clearly distinguishable from the vast expansion of federal power wrought by *Wickard* and could still survive even if *Wickard* is overruled.

Nor can this traditional reading of the commerce power be read to stifle the ability of the United States to respond to new shifts in technology. As early as 1875, the Court did not hesitate unanimously to hold that the power

of Congress to regulate extended to the telephone and the railroad as it had extended to the stagecoach nearly a century earlier. *Pensacola Tel. Co. v. Western Union Tel. Co.,* 96 U.S. 1, 9 (1876). There is nothing in the clause that by language or structure limits Congressional power to the modalities of interstate commerce known in 1787. But, by the same token, the rush of new technology does not require any extravagant translation of the Constitution to cover "the full range of economic (and hence social) life in America." Lawrence Lessig, *Translating Federalism: United States v. Lopez*, 1995 Sup. Ct. Rev. 125, 130 (1996). There is perfect fidelity to the Constitution without this dubious mistranslation. The important point here is to note that both local and national commerce receive the advantages of new technology, so that the accurate "translation" is that which preserves their relative balance in 1787 and for Chief Justice Marshall. The local sale of computers raises the same issue as the local sale of buggy whips. Recall that the scope of the power, as defined by Marshall, was enormous in 1824 when questions of the tariff and immigration were high on the American agenda. It is just wrong to claim that a new level of "interconnectedness" between intrastate and interstate activities, Tribe, at 811, requires a rethinking of the older doctrine. No new technological or demographic element was needed to catapult these elements to the fore after 1937. All that is needed is an application of the old rules to the new setting.

Thus, it is demonstrably false that the pre-1937 Court showed a "characteristic blindness" to the complexity of "economic reality." Tribe, at 811. Quite the opposite is true. The original Marshallian conception of the Commerce Clause does a far better job of balancing the competing interests within the contemporary federal system and national economy than does *Wickard*. The key function of government is to allow for the maintenance of a system of

ordered liberty, under which national markets can flourish over an economic and social infrastructure that is supplied by the states. That theme was well understood by Justice Jackson when he invoked the *dormant* Commerce Clause to strike down state regulations that interfered with the operation of a national competitive market in agricultural produce. *See, e.g., H.P. Hood v. DuMond*, 336 U.S. 525 (1949). *See also Dean Milk Co. v. City of Madison,* 340 U.S. 349 (1951).

In evaluating *Wickard* against this backdrop, its perverse anticompetitive and social consequences cannot be overlooked. The dispute that spurred *Wickard* was nothing more than a referendum vote by farmers on whether to accept wheat quotas proclaimed by the Secretary of Agriculture under the Agricultural Adjustment Act of 1938. The *Wickard* reading of the Commerce Clause allowed for the creation of nationwide cartels through which each increment in price reduced the nutritional content available to consumers, rich and poor, at a time when malnutrition was a far greater scourge than obesity. *See* Dale Heien & Cathy Roheim Wessells, *The Nutritional Impact of the Dairy Price Support Program,* J. Consumer Affairs 22 (Winter 1988): 201 (noting that the greatest impact of price supports was on welfare families whose consumption of calcium under regulation fell below recommended daily amounts, but which rose above those levels with deregulation). *See also* Kuo S. Huang, *Effects of food prices and consumer income on nutrient availability*, 31 Applied Economics, 367, 372 (1999) (noting impact of small income changes on nutrition); John Adrian & Raymond Daniel, *Impact of Socioeconomic Factors on Consumption of Selected Food Nutrients in the United States*, 59 (no. 1) Am. J. of Agricultural Economics 31 (1976).

The traditional reading of the Commerce Clause is sound because it stops such national abuses in their tracks. At the same time, it gives Congress the power to

prevent individual states from engaging in restrictive practices that block interstate commerce and upset the operation of competitive markets. Just that threat was posed by the New York legislation that was overridden in *Gibbons*. The claim that *Gibbons* is outdated and cannot apply to our current society is simply wrong. Indeed, *Gibbons'* rendering of the commerce power uncannily parallels contemporary economic theory. We live in a world with elaborate, nationwide transportation and communications networks for which it is proper for federal regulation to take priority over state regulation when necessary to keep national networks open from end to end.

Economic theory reflects this same understanding. The entire modern field of network economics deals with situations in which cooperation and coordination are needed among multiple actors, and it was created on the theory that *"these [network] markets cannot function as competitive markets."* Oz Shy, *The Economics of Network Industries* 6 (2001) (emphasis in original). And what are these network industries? They include, for starters, the telephone, email, Internet, airlines, and railroads. And, as Shy writes, we can "distinguish them from the market for *grain*, dairy products, apples and treasury bonds," *id.* at 1 (emphasis added), in which competitive solutions can be reached by the uncoordinated activities of separate firms.

It is no accident that the Agricultural Adjustment Act, discussed in *Wickard,* put in place a nationwide cartel that could *not* have been organized if the Commerce Clause had the reading it had received in *Gibbons*. In sum, the doctrine of translation in recognition of changed conditions applies to the Commerce Clause, if at all, only in reverse. Today, the United States is blessed with an unrivalled network of transportation and communication so that suppliers for all parts of the nation and the world can sell their goods in any and all markets. So long, therefore, as

the commerce power allows the Congress to keep the arteries of commerce clear from state encrustation, it is actually easier to have competitive product and service markets throughout the United States than it was in 1797 – but only if *Gibbons* remains the law.

The choice is clear. Uphold *Wickard* and reap nationwide cartels and authoritarian politics. Overrule *Wickard* and usher in competition and diversity. The Framers of the Constitution made this choice for us when they created a federal government of enumerated powers. We should stick to it today.

CONCLUSION

This Court should affirm the decision below.

Respectfully submitted,

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Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, *ET AL.*
Petitioners,
v.

ANGEL McCLARY RAICH, *ET AL.*,
Respondents,

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

Brief of The Leukemia & Lymphoma Society, Pain Relief Network, California Medical Association, AIDS Action Council, Compassion in Dying Federation, End-of-Life Choices, National Women's Health Network, Global Lawyers and Physicians, and AUTONOMY, Inc. as *Amici Curiae* in Support of Respondents

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INTEREST OF *AMICI CURIAE*[*]

Amici include organizations whose members, like Respondents, suffer from chronic, debilitating, and intensely painful medical conditions, as well as health care professionals who care for them, and associations committed to advancing understanding – in the medical community, legislatures, courts, and society at large – of pain and its humane medical treatment.

Although this case arises from the application of a particular federal statute, the Controlled Substances Act, to prohibit Respondents from pursuing a particular physician-recommended medical treatment, it raises issues not confined to that context, which are of urgent importance to *Amici*.

First, the principle that seriously ill individuals should have primary responsibility for determining, in consultation with the professionals who care for them, the course of their own medical treatment applies with special force when relief from extreme, intolerable pain is concerned. Intense pain is a direct assault on dignity and personality, and requiring an individual to forego effective relief and endure needless suffering is alien to our legal tradition and to the basic ethical norms that guide the practice of medicine.

Second, we are especially troubled that Respondents and those who treat them must make their medical decisions in the shadow of the *criminal* law. Centuries of Anglo-American law stand against the imposition of criminal liability on individuals for pursuing their own lifesaving pain relief and treatment.

As a practical matter, failure to recognize the difference between therapeutic use of a drug and its abuse has far-reaching, pernicious effects. As doctors, medical ethicists, and anthropologists have documented, the Nation remains in the grip of an "epidemic of undertreated pain." B. Rich, *A Prescription*

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[*]No counsel for any party authored any part of this brief. No person or entity, other than *Amici* and their counsel made a monetary contribution toward submission of this brief, which is filed with the parties' written consent.

for the Pain: The Emerging Standard of Care for Pain Management, 26 WM. MITCHELL L. REV. 1, 7 (2000).

As these commentators have explained, this serious, complex problem has many causes, but it is surely exacerbated by the thinness of the line separating provision of palliative care from violation of the criminal law – and by regulatory regimes that are often more reflective of fears and unfounded assumptions than of medical and scientific reality.

SUMMARY OF ARGUMENT

Although we do not believe that it is necessary or advisable to resolve this case on constitutional grounds, *Amici* submit that it cannot be resolved properly without an appreciation of the seriousness of the constitutional interests that Respondents' claim presents.

Without having settled the precise metes and bounds of the substantive right, this Court's precedents teach that the power asserted by the Government would be a serious encroachment on liberty interests safeguarded by the Due Process Clause. Not only is the right to make important decisions concerning the course of one's medical treatment of a piece with other rights recognized as "fundamental" in this Court's modern Due Process cases, the claim of medical necessity is analytically indistinguishable from rights of self-preservation, self-defense, and freedom from duress that were established in our tradition well before the Constitution was ratified. Moreover, Respondents' claim draws special force from the fact that the alternative to which the Government would relegate them is not some abstract loss of decisional autonomy, but rather a life of unremitting, unrelieved physical pain. Because the experience of pain can be so subversive of dignity – and even of the will to live – ethics and legal tradition recognize that individuals pursuing pain relief have special claims to non-interference.

Recognizing the substantiality of Respondents' liberty interest does not mean that the judgment below should be sustained exclusively or even primarily on that basis. But it

does lay bare the constitutional pitfalls of interpreting the CSA as the Government proposes: as authorizing prosecution of individuals, like Respondents, who would meet the stringent, long-established test for "necessity." Such a construction is unsound in any event, and to the extent a proper reading of the statute is in tension with *dicta* in *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483 (2001) ("*OCBC*"), we submit that it is the *dicta* that should give way.

We finally show that, contrary to the Government's suggestion, the reasons why Respondents possess marijuana are not "irrelevant" to the constitutional question on which review was sought: whether there is a substantial likelihood that the application here at issue is unlawful under Article I. The gravamen of Respondents' case is not merely that their activity is noncommercial or that its effect on interstate commerce is de minimis – although both are surely true – but that it is different in kind and in constitutional stature from that with which the Government seeks to have it "aggregated." Under this Court's precedents, questions concerning the scope of a particular congressional power are resolved in light of, not in isolation from, other important constitutional interests implicated. Given the seriousness of the infringement on liberty interests here (and the tenuous connection to any enumerated power), the power claimed by the Government could not be sustained as a necessary or proper interstate commerce regulation.

I. CRIMINAL RESTRICTIONS ON INDIVIDUALS' ABILITY TO OBTAIN MEDICAL TREATMENT FOR SEVERE PAIN AFFECT LIBERTY INTERESTS PROTECTED BY THE DUE PROCESS CLAUSE.

Although the case is presented as one principally involving the extent of Congress's legislative jurisdiction under the Interstate Commerce Clause, the Government's claimed power to prosecute persons such as Respondents Raich and Monson for possessing a drug determined, in consultation with their physicians, to be medically necessary to sustain themselves and

alleviate intractable suffering, also implicates individual liberties guaranteed by the Due Process Clause.

A. Individuals Have a Significant Liberty Interest in Avoiding Severe Pain and Obtaining Effective, Medically Appropriate Palliative Treatment.

As this case comes to the Court, it cannot seriously be contested that there exists a small but significant class of individuals who suffer from painful chronic, degenerative, and terminal conditions, for whom marijuana provides uniquely effective relief. *See* INSTITUTE OF MEDICINE, MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE ("IOM REPORT") 3-4, 179 (1999). Nor can it be disputed that Respondents Raich and Monson are members of that class. Although the Government seeks vaguely to denigrate these judgments via no fewer than 24 references to marijuana's merely "purported" medical benefits, it has never attempted, here or below, to adduce facts or data that would call into question the declarations of Respondents' physicians, *see* JA 48-51, 53, attesting that use of marijuana is literally indispensable to their health and well-being.

Although the Court need not – and therefore should not – settle here the contours of the Due Process right, this Court's cases leave no doubt that the power claimed by the Government, to brand Respondents criminals for pursuing that course, impinges on interests of "constitutional stature," *Washington v. Glucksberg*, 521 U.S. 702, 767 (1997) (Souter, J., concurring in judgment). *See United States v. Randall*, 104 Wash. D. Rep. 2249, 2253 n.29 (D.C. Super. 1976) ("a law which apparently requires a person to submit to deteriorating health without proof of a significant public interest to be protected raises questions of constitutional dimensions"); *see also Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 287-88 (1990) (O'Connor, J., concurring); *Lawrence v. Texas*, 123 S. Ct. 2472 (2003). The interest of persons who are dying or in agony to pursue treatment aimed at prolonging their lives and alleviating pain falls squarely along the "rational continuum" of enumerated and

unenumerated rights, *Poe v. Ullman*, 367 U.S. 497, 543 (1961) (Harlan, J., dissenting), that constitutional "liberty" has been construed to encompass.

As much was essentially conceded in the Brief submitted by the United States in *Glucksberg* – and found recognition in each of the opinions in that case and its companion, *Vacco v. Quill*, 521 U.S. 793 (1997). The United States there acknowledged that, for terminally ill adults, there is

> a constitutionally cognizable liberty interest in avoiding the kind of suffering experienced by the plaintiffs in this case. That liberty interest encompasses an interest in avoiding not only severe physical pain, but also the despair and distress that comes from physical deterioration and the inability to control basic bodily or mental functions in the terminal stage of an illness.

Br. for U.S. as *Amicus Curiae*, No. 96-110, at 8.

Although the opinions in those cases declined to recognize a "generalized right to 'commit suicide,'" 521 U.S. at 736 (O'Connor, J., concurring), they placed substantial emphasis on the facial nature of the constitutional challenges presented – and on the fact that the plaintiff parties, although denied assistance in ending their lives, had not claimed to have been prevented from obtaining adequate palliative care. Thus, Justice O'Connor underscored that the Court's decision did not foreclose a claim by "a patient * * * suffering from a terminal illness and * * * experiencing great pain" who had not been permitted to obtain "medication, from qualified physicians, to alleviate that suffering," 521 U.S. at 736, and Justice Breyer's opinion explicitly recognized that the plaintiffs had a liberty interest in "avoidance of unnecessary and severe physical suffering," albeit one that was not "directly at issue," 521 U.S. at 792, because plaintiffs' access to pain relief was uncontested. Both Chief Justice Rehnquist's majority opinion in *Glucksberg* (521 U.S. at 735 n.24) and his concurrence in *Vacco* accepted that the Court's decisions did "'not foreclose the possibility that some

applications of the [challenged] statute[s] may impose an intolerable intrusion on the patient's freedom.'" 521 U.S. at 809 n.13 (quoting 521 U.S. at 751-52 (Stevens, J., concurring in judgments)). *See also id.* at 745 (Stevens, J.) ("Avoiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly '[a]t the heart of [the] liberty' protected by the Due Process Clause") (citations omitted).

Indeed, to the extent that Respondents' interests differ from those of the claimants hypothesized in *Glucksberg*, it is in that they do not seek to escape unbearable suffering by *ending* their lives with their physicians' help. They seek to *prolong* their lives by using a drug, under doctors' care, that, among its other benefits, enables them to tolerate other necessary therapies. *Compare* 521 U.S. at 715-16 (discussing State interest in safeguarding life); *see also Cruzan*, 497 U.S. at 283 n.10.

This emphasis on individual medical circumstances – and on the individual interest in avoiding pain and suffering – follows the path charted in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). In that case, the Court sustained against a Due Process challenge the application of a Massachusetts statute mandating smallpox vaccination. But in so ruling, the Court stressed that it was not presented with the case of an individual who claimed to "be a[n un]fit subject of vaccination, or that vaccination, by reason of his then condition, would seriously impair his health, or probably cause his death." *Id.* at 38. The Court strongly suggested, *id.* at 39, that a different result would obtain in the case of an adult whose "particular condition of * * * health or body" would make vaccination "cruel and inhuman in the last degree." Its resolution of Jacobson's case, the decision cautioned (*id.*), was:

> not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned.

Nor can Respondents' interest be meaningfully distinguished from those recognized in cases addressing governmental barriers to abortion, *see Stenberg v. Carhart*, 530 U.S. 914, 921 (2000); *Planned Parenthood, Southeastern Pa. v. Casey*, 505 U.S. 833, 849 (1992) (plurality opinion), or efforts to administer medicine against an individual's wishes, *see Cruzan*, 497 U.S. at 278-79; *see also United States v. Sell*, 539 U.S. 166, 179 (2003) ("an individual has a constitutionally protected liberty 'interest in avoiding involuntary administration of antipsychotic drugs'") (quoting *Riggins v. Nevada*, 504 U.S. 127, 134 (1992)); *Washington v. Harper*, 494 U.S. 210, 227 (1990).[1]

Governmental intrusions on individual decisionmaking in those circumstances are carefully scrutinized both because "our notions of liberty are inextricably entwined with our idea of *physical* freedom and self-determination," *Cruzan*, 497 U.S. at 287 (O'Connor, J., concurring) (emphasis added), and because they involve matters that are "central to personal dignity and autonomy." *Glucksberg*, 521 U.S. at 745 (Stevens, J., concurring in judgment); *see Casey*, 505 U.S. at 852 (a pregnant woman "is subject to anxieties, to physical constraints, to pain that only she must bear * * * * Her suffering is too intimate and personal for the State to insist, without more, upon its own vision of the woman's role").

Legal recognition of the principle that "[e]very human being of adult years and sound mind has the right to determine what shall be done with his own body," *Schloendorff v. Society of New York Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.), predates modern constitutional jurisprudence. In 1765, Blackstone described a common law right to bodily integrity as including a right to "the preservation of a man's health from such practices as may prejudice or annoy it." W. BLACKSTONE, 1 COMMENTARIES ON THE LAWS OF ENGLAND *134. And over

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[1] Notably, *Riggins* and *Sell* recognized liberty interests – and carefully scrutinized governmental impositions – without expressly describing the interests as "fundamental."

a century ago, this Court observed that: "No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

That the Government would require Respondents and other individuals to endure *pain* is also constitutionally important. The imperative to avoid or alleviate severe pain is a "consensus value" shared by – indeed, central to – virtually all human beings.[2] Few interests more clearly reflect the "'basic values that underlie our society.'" *Moore v. City of East Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion) ((quoting *Griswold v. Connecticut*, 381 U.S. 479, 501 (1965) (Harlan, J., concurring)).

Accordingly, the Due Process Clause has been construed to require the government to attend to the medical needs of those within its custody, *Revere v. Massachusetts Gen. Hosp.*, 463 U.S. 239, 244 (1983), and cases involving the guarantees enumerated in the Bill of Rights attach special importance to governmental complicity in – or indifference to – physical suffering. In *Estelle v. Gamble*, 429 U.S. 97, 103-04 (1976), this Court held that because infliction of unnecessary suffering "is inconsistent with contemporary standards of decency," deliberate indifference to inmates' medical needs – whether manifested "by prison doctors * * * or by prison guards in intentionally denying or delaying access to medical care or intentionally interfering with the treatment once prescribed" – violates the Eighth Amendment. *See also Hudson v. Macmillan*, 503 U.S. 1, 6-9 (1992) (reaffirming that the Eighth Amendment proscribes "unnecessary and wanton infliction of pain," even if no serious physical injury eventuates); *Louisiana ex rel. Francis*

[2]S. Kreimer, *The Second Time as Tragedy: the Assisted Suicide Cases and the Heritage of Roe v. Wade*, 24 HASTINGS CONST. L. Q. 863, 895 (1997). *See also* S. HAMPSHIRE, INNOCENCE AND EXPERIENCE 90 (1989) (identifying physical pain and torture as among "the great evils of human experience, reaffirmed in every age").

v. Resweber, 329 U.S. 459, 463 (1947) ("the traditional humanity of modern Anglo-American law forbids the infliction of unnecessary pain in the execution of the death sentence"); *Chavez v. Martinez*, 538 U.S. 760, 796 (2003) (Kennedy, J, concurring in part and dissenting in part).

The law's special concern about pain also reflects the extent to which physical suffering can fundamentally inhibit its sufferers' ability to experience life, to think clearly, and to exercise other fundamental rights. Pain, which Dr. Albert Schweitzer called the most terrible of all "the lords of mankind," can "extend[] beyond the physical" to "totally occup[y] the psychic world." S. Kreimer, 24 HASTINGS L. Q. at 895. *See id.* at 895 n. 157 ("'[I]n serious pain the claims of the body utterly nullify the claims of the world'") (quoting E. SCARRY, THE BODY IN PAIN 33, 54 (1985). *See Riggins*, 504 U.S. at 143-44 (Kennedy, J., concurring) (discussing risks that antipsychotic medication could impair criminal defendant's exercise of trial rights). Recognizing the corrosive effect of pain on individual reason and autonomy, this Court has stressed the "inherent[] untrustworth[iness]" of coerced confessions, *Dickerson v. United States*, 530 U.S. 428, 433 (2000), and severe pain's incompatibility with "a rational intellect and a free will," *Mincey v. Arizona*, 437 U.S. 385, 398 (1978). *Cf. Brown v United States*, 256 US 335, 343 (1921) ("Detached reflection cannot be demanded in the presence of an uplifted knife") (Holmes, J.).

B. Legal And Ethical Tradition Stand Against Criminalizing the Palliative Care Decisions of Seriously Ill People And Their Physicians.

The individual interest in access to means to alleviate physical suffering is strongly reinforced by legal and ethical traditions. *See Glucksberg*, 521 U.S. at 725 (describing "right assumed in *Cruzan*" as the fruit of a "long legal tradition protecting the decision to refuse unwanted medical treatment"); *But cf. Lawrence*, 123 S. Ct. at 2479 ("'[H]istory and tradition are the starting point but not in all cases the ending point of the

substantive due process inquiry'") (quoting *Sacramento v. Lewis,* 523 U.S. 833, 857 (1998) (Kennedy, J., concurring)).

For centuries, Anglo-American law has recognized that proof that an act was necessary as a matter of self-preservation precludes imposition of criminal liability – even for conduct that causes serious harm and plainly violates positive law (and even where no exception has been codified within the four corners of the statute, *see infra*). *See* E. Arnolds & N. Garland, *The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil*, 65 J. CRIM. L. & CRIMINOLOGY, 289, 291 (1974)) ("The concept of necessity as a defense to prosecution has been 'anciently woven into the fabric of our culture'") (quoting J. HALL, GENERAL PRINCIPLES OF THE CRIMINAL LAW 416 (2d ed. 1960)); P. Glazebrook, *The Necessity Plea in English Common Law*, 30 CAMB. L.J. 87, 93 (1972) (citing *Reninger v. Fagossa*, 1 Plowden, 75 Eng. Rep. (1551)); C. Wells, *Necessity and the Common Law*, 5 OX. J. LEGAL STUD. 471, 472 (1985). Indeed, the Constitution has been construed to require that abortion restrictions contain an exemption for procedures that are medically necessary, even when supported by governments' "compelling" interest in potential life post fetal-viability. *E.g.*, *Stenberg*, 530 U.S. at 921; *id.* at. 951 (O'Connor J., concurring).

Moreover, principles of medical ethics require that physicians and other health care providers take measures to relieve the pain and suffering of those under their care – including recommending alternative therapies for individual patients for whom conventional approaches have proved ineffectual. Allowing a patient to experience unnecessary pain or suffering is considered substandard medical practice, regardless of the nature of the patient's condition or the goals of medical intervention. D. MORRIS, THE CULTURE OF PAIN 191 (1991) (observing that "not relieving pain brushes dangerously close to the act of willfully inflicting it").[3]

[3] *See* L. Post, *et al.*, *Pain: Ethics, Culture, and Informed Consent to Relief*, 24 J. LAW, MED. & ETHICS 348 (1996) ("Even when cure is impossible, the physician's duty of care includes palliation"); S. Wanzer, *et al.*, *The Physician's Responsibility Toward Hopelessly Ill Patients: A Second Look*, 320 NEW ENGLAND J. MED. 844 (1989) ("[t]o allow a patient to experience unbearable pain or suffering is unethical medical practice * * * * [and t]o withhold any necessary measure of pain relief in a hopelessly ill person out of fear * * * of possible legal repercussions is unjustifiable"); R. Edwards, *Pain and the Ethics of Pain Management*, 18 SOC. SCI. MED. 515 (1984).

There is a long tradition, in this Court's decisions and in the Nation's laws, of respecting and facilitating such medical decisionmaking. *See Harper*, 494 U.S. at 223 ("we will not assume that physicians will prescribe * * * drugs for reasons unrelated to the medical needs of the patients; indeed, the ethics of the medical profession are to the contrary"); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002) (declining to assume that physicians would prescribe "unnecessary medications"); *see also* 37 Fed. Reg. 16,503, 16,504 (1972) (FDA does not "regulate or interfere with the practice of medicine"); *accord* 21 U.S.C. § 396; 42 U.S.C. § 1395; *cf. Stenberg*, 530 U.S. at 937 ("*Casey*'s words 'appropriate medical judgment' must embody the judicial need to tolerate responsible differences of medical opinion").

For example, the Court in *Thompson* recognized that sale of "compounded" drugs, *i.e.*, those whose ingredients are altered by a pharmacist or doctor, served the "important interest" in assuring "that patients with particular needs may obtain medications suited to those needs," 535 U.S. at 369, and the FDA has long "recognized the legality of using drugs for purposes other than those for which they have been found safe and effective." *FTC v. Simeon Mgmt. Corp.*, 532 F.2d 708, 717 (9th Cir. 1976); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 n.5 (2001) ("'[o]ff-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize'") (quoting J. Beck & E. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71 (1998)).

By contrast, there is no tradition whatsoever of bringing the weight of the criminal law down on individuals who pursue alternative therapies for relief from pain and suffering when no lawful or conventional medication is effective. *See Lawrence*, 123 S. Ct. at 2480 (noting heightened concerns when policies are enforced through "operation of] the criminal law"). Proscription of particular drugs was largely a twentieth century innovation, *see, e.g.*, S. DUKE & A. GROSS, AMERICA'S LONGEST WAR 83-86 (1992) – and even then, the primary legislative focus has been on preventing fraudulent commercial marketing, *see* 21 U.S.C. § 301 *et seq.*, and distribution for non-medical use, *i.e.*, to recreational (or habitual) users, *see infra*; *cf. United States v. Jin Fuey Moy*, 241 U.S. 394, 401 (1916).

Indeed, even if the interest here at issue is described, inappropriately, as a right to possess *marijuana* for medical purposes, the historical evidence on the government's side would be underwhelming. For the first 170 years of this Nation's history, there was no State or federal law preventing the recommendation of marijuana for medical purposes. *See* Marijuana Tax Act, Pub. L. No. 75-238, 50 Stat. 551 (1937) (distinguishing between medical and non-medical transactions); L. Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J. LAW, MED. & ETHICS 55, 59 (2003) (noting that "the United States Pharmacopeia (U.S.P.), which Congress has cross-referenced in other statutes as a source for information about therapeutic products, had listed marijuana as a drug for almost a century").

The first federal statute to categorically proscribe marijuana, in 1970, did not do so because of any determination that it lacked therapeutic benefit, *see* pp.20-24, *infra*; *see generally* R. BONNIE & C. WHITEBREAD, THE MARIJUANA CONVICTION 246 (1999), and in more recent years, voters, legislators, and courts in the majority of States have reaffirmed, with varying degrees of assertiveness, that those who use marijuana for genuinely medical reasons, when alternatives have been exhausted, should

not be subjected to criminal punishment. *Cf. Penry v. Lynaugh*, 492 U.S. 302, 331 (1989) ("The clearest and most reliable objective evidence of contemporary values is the legislation enacted by the country's legislatures") (citations omitted).[4]

The experience with laetrile (Pet. Br. 26, citing *United States v. Rutherford*, 442 U.S. 544 (1979)) is not at all in point. First, and most important, the claimants in *Rutherford* were not denied access to laetrile in-state, let alone required to run the gauntlet of the criminal law. Rather, as the Court observed:

> Whether Laetrile should be freely accessible to cancer patients has been a frequent subject of political debate. Seventeen States have legalized the prescription and use of Laetrile for cancer treatment within their borders, and similar statutes have been defeated in 14 other States.

442 U.S. at 554 n.10. Plaintiffs in that case sought "to enjoin the Government *from interfering with the interstate shipment and sale* of Laetrile," 442 U.S. at 544 (emphasis added). Far from authorizing prosecution of cancer patients who used laetrile (or their doctors), the statute at issue in *Rutherford*, the Food Drug and Cosmetic Act, addresses the "introduc[tion] or deliver[y] * * * *into interstate commerce*" of unapproved "new drugs," 21 U.S.C. § 355(a) (emphasis added), and, as noted above, has always been understood not to "regulate or interfere with the practice of medicine." 37 Fed. Reg. at 16,504.

Second, the government in *Rutherford* put on substantial scientific evidence that the drug at issue, which was to be marketed as a *cure* for cancer, would not be effective for that purpose, and invoked legitimate concerns that patients would be

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[4]Nine States have laws exempting therapeutic use; two others have recognized by judicial decision a medical necessity defense to prosecutions under drug laws; and numerous others have adopted measures with less practical effect, but which take a less rigid approach than the one claimed for the federal law here. *See* Resp.Br. n.1. Even in States where positive law remains unmodified, prosecutions of individuals situated similarly to Respondents are nearly unheard-of. *See Lawrence*, 123 S. Ct. at 2479.

induced to "reject[] conventional therapy in favor of a drug with no demonstrable curative properties," 442 U.S. at 556; *see also id.* at 553 n.9. By contrast, the primary evidence of marijuana's therapeutic value is not as a cure, but rather as a means for individuals suffering from serious illness to better respond to and tolerate potentially lifesaving conventional treatments, *see* IOM REPORT at 154, and the Government here offered no disproof of Respondents' evidence that marijuana is effective for them (in ways that conventional therapies alone have failed).

Finally, the interests on the Government's side are unusually insubstantial. *Compare Glucksberg*, 532 U.S. at 788-89 (Souter, J., concurring) (acknowledging weight of interests on both sides of assisted suicide debate). Respondents' claims present no conflict – as do most of the other liberty interests so far discussed – between the wishes of the individual and the dictates of medical judgment, *see Sell*, 539 U.S. at 179-80; *Harper*, 494 U.S. at 226-27, medical ethics, *Glucksberg*, 521 U.S. at 731, or broader societal interests in life, *id.* at 728; or "potential life," *Stenberg*, 530 U.S. at 921; *cf. Rutherford*, 442 U.S. at 557 (noting FDA Commissioner's conclusion that widespread distribution of laetrile "would lead to needless deaths and suffering among * * * patients characterized as 'terminal' who could actually be helped by legitimate therapy'") (quoting 42 Fed. Reg. at 39,805). Indeed, these interests uniformly *support* permitting access to drugs in circumstances like Respondents', that have proven the only effective means of treating an agonizing, debilitating or life-threatening condition.[5]

[5]Even if broader "symbolic" purposes could ever justify burdening individuals in Respondents' position – or branding them criminals – *but see Casey*, 505 U.S. at 852; *Lawrence*, 123 S. Ct. at 2379, the authoritative IOM REPORT, commissioned by the Office of National Drug Control Policy, found "no convincing data to support th[e] concern that sanctioning medical use of marijuana might increase its use among the general population" and "no evidence that the medical marijuana debate has altered adolescents' perceptions of the risks associated with marijuana use," *id.* at 104.

II. THE CSA SHOULD NOT BE CONSTRUED TO AUTHORIZE PUNISHMENT OF INDIVIDUALS WHO CAN SHOW MEDICAL NECESSITY.

This case raises serious constitutional questions only if – as the Government argues and as *OCBC* suggested, in *dicta* – the CSA does not allow individuals like Respondents to invoke medical necessity to shield themselves from sanctions. Because there is no sign Congress intended to punish gravely ill individuals for marijuana use under medical supervision, after conventional therapies are ineffectual, the Court should reject the Government's position.

In addition to reflecting a correct understanding of the CSA, that approach would be consistent with this Court's long practice of deferring difficult constitutional questions until they are squarely and unavoidably presented. *E.g., Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988); *Ashwander v. TVA*, 297 U.S. 288, 348 (1936) (Brandeis, J., concurring).

The usual prudence is especially warranted in this case, because it raises questions about the scope of individual liberties that the Court has only begun to delineate, *cf. Glucksberg*, 521 U.S. at 781-82 (Souter, J., concurring), and because rulings concerning the scope of Congress's Article I powers can reverberate far beyond the case and statute at hand.

Refraining from reaching the constitutional questions here would likewise reflect the appropriate relationship between this Court and Congress. There is no indication in the CSA that Congress intended the statute to reach as far as the Government now claims, or that it specifically considered the plight of individuals for whom use of a controlled substance is genuinely necessary as a therapeutic last resort. The Court should not assume that Congress intended to act so sweepingly; rather, and consistent with its prior practice, *see Jacobson*, it should demand that Congress express its (supposed) intent to uncompromisingly criminalize gravely ill individuals' medical

choices – before resolving the constitutional questions such an enactment would present.

A. The Necessity Doctrine is a Settled Part of Federal Law.

As this Court recognized in *United States v. Bailey*, 444 U.S. 394, 410 (1980), courts have "traditionally" recognized a defense of necessity in "situation[s] where physical forces beyond the actor's control rendered illegal conduct the lesser of two evils," leaving the actor "no reasonable, legal alternative to violating the law," *id.* *See also* MODEL PENAL CODE § 3.02(1)(a) ("the harm or evil sought to be avoided by such conduct is greater than that sought to be prevented by the law defining the offense charged").[6] It precludes imposition of criminal liability on an individual who: (1) was faced with a choice of evils and chose the lesser evil; (2) acted to prevent imminent harm; (3) reasonably anticipated a direct causal relationship between her conduct and the harm to be averted; and (4) had no legal alternative prevent the harm.[7] The defense has roots stretching back more than 700 years and has been

[6]In *Bailey*, all eight participating Justices assumed, as lower courts had held, see 444 U.S. at 410, that necessity or duress could provide a defense to a prison inmate charged with escape even though the relevant statute, 18 U.S.C. § 751(a), did not expressly so provide. *See, e.g.*, 444 U.S. at 397, 410-11; *id.* at 427-28 (Blackmun, J., dissenting). The majority held that the defendants could not avail themselves of the defense only because "in the context of prison escape, the escapee is not entitled to claim a defense of duress or necessity unless and until he demonstrates that, given the imminence of the threat, violation of § 751(a) was his only reasonable alternative." *Id.* at 410.

[7]*See United States v. Sued-Jimenez*, 275 F. 3d 1, 6 (1st Cir. 2001); *United States v. Cassidy*, 616 F.2d 101, 102 (2d Cir.1979); *United States v. Romano*, 849 F.2d 812, 816(3d Cir. 1988); *United States v. Cassidy*, 616 F.2d 101, 102 (4th Cir. 1979); *United States v. Gant*, 691 F.2d 1159, 1162 (5th Cir. 1982); *United States v. Milligan*, 17 F.3d 177, 181 (6th Cir.1994); *United States v. Jocic*, 207 F.3d 889, 892 (7th Cir.2000); *United States v. Griffin*, 909 F.2d 1222, 1224 (8th Cir. 1990); *United States v. Arellano-Rivera*, 244 F.3d 1119, 1125 (9th Cir. 2001); *United States v. Turner*, 44 F.3d 900, 902 (10th Cir. 1995); *United States v. Deleveaux*, 205 F.3d 1292, 1297 (11th Cir.2000); *United States v. Mason*, 233 F.3d 619 (D.C. Cir. 2000).

consistently recognized in this country for centuries.[8]

Like its companions, duress and self-defense, necessity avoids punishment of persons who commit acts violative of the criminal law, but who do so under circumstances or for reasons that the legislature did not deem (or would not have deemed) blameworthy. *See* J. Parry, *The Virtue of Necessity: Reshaping Culpability and the Rule of Law*, 36 HOUSTON L. REV. 397, 457 (1999); G. FLETCHER, RETHINKING CRIMINAL LAW 792 (1978). This role as a time-honored check against reflexive punishment of those who have acted in circumstances arguably not within the contemplation of the positive law suggests that courts should approach with caution the argument that a legislature has foreclosed a necessity defense, by making its own balance of competing values. *See, e.g.*, MODEL PENAL CODE, § 3.02(1)(c) (legislative purpose to exclude the justification must "plainly appear" in statute).

B. *OCBC* Should Not Preclude Respondents from Invoking Medical Necessity.

In *OCBC*, the Court held that "medical necessity is not a defense to manufacturing and distributing marijuana." 532 U.S. at 494. The respondents in that case were a medical marijuana cooperative and its executive director, who had "distribut[ed] marijuana to numerous persons" and sought to justify their own violations of the CSA based on the medical needs of third-party patients, none of whom was before the Court. *See* 532 U.S. at 487. As Justice Stevens explained in concurrence, the

[8]*See Note, Necessity: The Right to Present a Recognized Defense*, 21 NEW ENG. L. REV. 779, 781-84 (1986); M. Conde, *Necessity Defined: A New Role in the Criminal Defense System*, 29 U.C.L.A. L. REV. 409 (1981); Arnolds & Garland, *supra*, p. 10; G. Williams, *The Defence of Necessity*, 6 CURRENT LEGAL PROBLEMS 216, 224 (1953). For early examples from this country, see *The William Gray*, 29 F. Cas. 1300 (C.C.D.N.Y. 1810); *United States v. Ashton*, 24 F. Cas. 873 (C.C.D. Mass. 1834); *Surocco v. Geary*, 3 Cal. 69 (1853); *Conwell v. Emrie*, 2 Ind. 35 (1850); *Field v. City of Des Moines*, 39 Iowa 575 (1874); *Seavey v. Preble*, 64 Me. 120 (1874); *State v. Jackson*, 53 A. 1021 (N.H. 1902).

cooperative and its director did not qualify for the necessity defense under its standard formulation because they had not themselves been confronted with an unavoidable "choice of evils," but had instead "elected to become distributors" to patients. 532 U.S. at 500 n.1.

Respondents' situation is markedly different from that of the marijuana distributors in *OCBC*. Raich and Monson *personally* face the choice between physical suffering and breaking the law, and did not choose their afflictions. Both, moreover, consulted with their physicians, tried numerous lawful medications without success before turning to marijuana, and use the drug pursuant to their physicians' recommendations and under their supervision. J.A. 51, 53, 55-59, 65-91.

The viability of a necessity defense for individuals themselves afflicted with serious illness and chronic pain was not before the Court in *OCBC*, and was not decided in that case. The majority opinion does, however, contain *dicta* on which the Government now seizes. First, the Court termed it an "open question whether federal courts ever have authority to recognize a necessity defense not provided by statute." 532 U.S. at 490. Second, the Court said that "Congress has made a determination that marijuana has no medical benefits worthy of an exception." *Id.* at 493. *See also id.* at 499 ("in the Controlled Substances Act, the balance already has been struck against a medical necessity exception"). And, finally, the Court stated in a footnote that "nothing in our analysis suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act." *Id.* at 494 n. 7. None of these *dicta* should preclude the Court from recognizing necessity here.

First, there has never been any requirement that affirmative defenses like necessity, duress, or self-defense be spelled out by statute. To the contrary, such defenses have been "routinely allowed against federal criminal prosecutions without explicit statutory basis." G. CALABRESI, A COMMON LAW FOR THE AGE

OF STATUTES 287 n.33 (1982).[9] The necessity defense has been understood to accord both with legislative expectations, see *Bailey*, 444 U.S. at 416-17 n.11 (recognizing "that Congress in enacting criminal statutes legislates against a background of Anglo-Saxon common law"); *United States v. Schoon*, 971 F.2d 193, 197 (9th Cir.1991) ("by allowing prisoners who escape a burning jail to claim the justification of necessity, we assume the lawmaker, confronting this problem, would have allowed for an exception to the law proscribing prison escapes"), and basic notions of fairness and human decency, *supra*, pp. 3-14; *see also Jacobson*, 197 U.S. at 39 ("The reason of the law in [case where compulsory vaccination would cause illness] should prevail over its letter") (citation omitted).

Because doctrines such as self-defense, necessity and duress are traditionally (and, in the federal system, invariably) defined and administered by the courts, the CSA's silence by no means cuts against a necessity defense for individuals who can satisfy its requirements. Indeed, to our knowledge Congress has never enacted a statute that explicitly foreclosed the common law defenses of necessity, duress, or entrapment, nor – at least prior to the decision in *OCBC* – had this Court ever found that a federal statute had abrogated any of these defenses. *Cf.* D. Meltzer, 2002 S. CT. REV. at 355 (noting that "insanity defense * * * was a common law rule until Congress in 1984 supplanted the judge-made defense with a statutory version"). Nothing in the CSA's text or history warrants singling it out as the only federal criminal prohibition against which a citizen cannot assert a necessity defense – despite satisfying the traditional elements.

Furthermore, in many circumstances, it would raise serious constitutional questions for a government to prosecute a person

[9]The same is true of other settled (but also statutorily unmentioned) federal defenses, including entrapment, selective prosecution, infancy, outrageous government conduct, public authority, impossibility, and vindictive prosecution. *See, e.g.*, D. Meltzer, *The Supreme Court's Judicial Passivity*, 2002 SUP. CT. REV. 343, 355; P. Marcus, *The Due Process Defense in Entrapment Cases: The Journey Back*, 27 AM. CRIM. L. REV. 457 (1990).

who had been forced at gunpoint to open a bank vault without allowing him recourse to a duress defense, or to bar a necessity plea by a person charged with larceny for taking his neighbor's hose to put out a potentially deadly fire. *Cf.* 3 W. BLACKSTONE, COMMENTARIES at 3 ("Self-defense * * * is justly called the primary law of nature, (and therefore) it is not, neither can it be * * * taken away by the law of society"); *Jackson v Senkowski,* 817 F. Supp. 6, 7 (S.D.N.Y. 1993) (noting that "[a]ll states appear to recognize a defense of self-defense," and that "[o]ne might well be deprived of liberty without due process if incarcerated for attempting to defend one's life").[10]

There is in fact no evidence that Congress intended to punish persons like Respondents – individuals actually faced with a wrenching "choice of evils," between violating the drug laws or continuing to experience severe physical pain. The *dicta* in *OCBC* are in error to the extent they suggest that the CSA worked such a result, and they should not be extended in a case involving persons actually facing such a choice. First, there is nothing in the text of the statute that arguably addresses the necessity defense (or other potentially relevant defenses). Nor is Congress's placement of a drug on Schedule I equivalent to a finding that it has no "accepted medical use," 21 U.S.C. § 812(b). When Congress directly classifies a drug, as it did marijuana in 1970, it is not bound by the criteria in section 812(b). In fact, Congress has directly placed drugs on Schedule I precisely because they *did* have an accepted medical use, and for that very reason could not, consistently with the terms of §

[10]To the extent that *OCBC* implied that constitutional avoidance applies only in situations where the meaning of particular *words* is disputed, precedent is to the contrary. The preference for a constitutionally unproblematic alternative construction is no less applicable to cases where the uncertainty relates to whether the legislature intended to abrogate or retain a traditional limitation or requirement – whether or not there are individual words whose meaning might otherwise be described as "ambiguous." *Cf. Feltner v. Columbia Pictures Television, Inc.*, 523 U.S. 340, 358 (1998) (Scalia, J., concurring in judgment); *Staples v. United States,* 511 U.S. 600 (1994) (silence is inadequate to infer elimination of *mens rea* requirement).

812, be reclassified *administratively.*[11] Even more clearly, the scheduling decision implies no legislative judgment regarding the exceptional, extenuating circumstances of individuals – who are seriously ill and have exhausted conventional, alternative therapies – in circumstances far removed from the paradigmatic "recreational" or "abusive" drug user.[12]

The suggestion that Congress's scheduling decision should be understood as a "finding" about a drug's lack of therapeutic value (or unsafety) is especially implausible in the case of marijuana. Months before enacting the CSA, and citing the "lack of * * * authoritative * * * information involving the

[11]*See* Pub. L. 98-329, 98 Stat. 280 (1984) (transferring methaqualone from Title II to Title I despite accepted medical use and prior FDA approval); H.R. Rep. No. 98-534 at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 543-44 (DEA "may not, in the absence of Congressional action, subject drugs with a currently accepted medical use in the United States to Schedule I controls").

[12]Any claim that placement on Schedule I reflects a "determination" that marijuana use is unsafe in every individual case is irreconcilable with the fact that the federal government has operated, for most of the statute's life, a Compassionate Investigative New Drug ("I.N.D.") Program, whereby patients whose serious medical conditions could be alleviated only by marijuana are supplied with a government-grown supply of the drug. Several patients still receive a regular supply of medical marijuana from the United States under this program, which was initiated as part of a settlement of a lawsuit filed by glaucoma patient Robert Randall after he was acquitted of unlawful marijuana cultivation based upon a showing of necessity. *See supra,* p.4; R. Isenberg, *Medical Necessity As a Defense to Criminal Liability: United States v. Randall,* 46 GEO. WASH. L. REV. 273 (1978). By 1983, the FDA had approved seventy-nine I.N.D. plans to permit therapeutic use of marijuana for conditions including chemotherapy-induced nausea and vomiting, glaucoma, spasticity, and weight loss. *See* H. JONES & P. LOVINGER, THE MARIJUANA QUESTION 136 (1985); *see also United States v. Burton*, 894 F.2d 188, 191 (6th Cir. 1990) (rejecting glaucoma patient's necessity defense, on the ground that the I.N.D. program at that time provided a reasonable legal alternative to violating the law). Despite the program's name, these plans were *not* clinical trials to test the drug for eventual approval; rather they were means for the government to administer a program of medical use by patients demonstrating necessity. *See Despite Marijuana Furor, 8 Users Get Drug from the Government*, N.Y. Times A33 (Dec. 1, 1996). The government has not allowed any new patients into the program since 1992. *Id.*

health consequences of using marihuana," Congress passed the Marijuana and Health Reporting Act, Pub. L. No. 91-296, which directed the HEW Secretary to prepare a report, within 90 days (and annually thereafter), containing "current information on the health consequences of using marihuana" and "such recommendations for legislative and administrative action as he may deem appropriate." On August 14, 1970, during the CSA debates – but before the report was completed – HEW advised Congress that because "there [was] still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marijuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4579.

Consistent with that recommendation, Congress placed marijuana on Schedule I, but, to resolve uncertainty, established a bipartisan Commission on Marihuana and Drug Abuse (later known as the "Shafer Commission"), *see* Act of Oct. 27, 1970, Pub. L. No. 91-513, § 601, to prepare (1) a report on "the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological" and (2) proposals for legislation and administrative action, *id.* In its report, the Shafer Commission recommended that Congress amend the CSA, and States amend their laws, so that *any* possession of marijuana for personal use would not subject the possessor to punishment, even as a misdemeanor. *See* MARIJUANA: A SIGNAL OF MISUNDERSTANDING; FIRST REPORT OF THE NATIONAL COMMISSION ON MARIHUANA AND DRUG ABUSE 152-53 (1972). While Congress did not adopt this recommendation, this course of action leaves no room for arguing that the initial scheduling decision should be construed as a legislative determination that marijuana is unsafe for all individuals, let alone that traditional common law principles, such as necessity, should be inapplicable.

Nor is recognizing the common law doctrine of necessity inconsistent with the statutory procedures for administrative reclassification of drugs. Administrative reclassification is a process that addresses the availability of drugs for general medical use, not the appropriateness of its use by an individual patient who has no other alternative to avoid imminent harm. *Cf. Thompson*, 535 U.S. at 361 (noting importance of compounded drugs for "individual patient[s]" whose needs are not met by commercially available, mass-produced medications).[13] In the context of administrative reclassification, the statutory criteria of "currently accepted medical use" serves a fundamentally different purpose than does the necessity defense, and it is unreasonable to expect a patient who demonstrates true legal necessity to await a drug's administrative reclassification.[14] Rather, the necessity doctrine has always operated as a "safety valve," to accommodate urgent needs of individuals facing imminent harm and to prevent rigid application of the law in extreme circumstances. *See* Arnolds & Garland, *supra* at 291. There is no sign that Congress in 1970 intended to take away that traditional safety valve.

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[13]In denying a petition to reclassify marijuana in 2001, 66 Fed. Reg. 20,038, 20,047 (Apr. 18, 2001), the DEA stated that:

> There is suggestive evidence that marijuana may have beneficial therapeutic effects in relieving spasticity associated with multiple sclerosis, as an analgesic, as an antiemetic, as an appetite stimulant and as a bronchodilator, but there is no data from controlled clinical trials to support a new drug application for any of these indications. Data of the risks and potential benefits of using marijuana for these various indications must be developed to determine whether botanical marijuana, or any cannabinoid in particular, has a therapeutic role.

[14]In *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994), the court upheld a five-part test formulated by the DEA to determine whether a drug is in "currently accepted medical use," and therefore eligible for administrative re-scheduling – one which required: a "known and reproducible" chemical composition; adequate studies of safety and efficacy; acceptance by "qualified experts," and "widely available" scientific evidence. *Id.* at 1135 (citing 57 Fed. Reg. at 10,506).

Nor can there be any doubt that Respondents satisfy the traditional requirements of the necessity doctrine. Persons who violate the CSA's letter by possessing medical marijuana – on a physician's advice after exhausting lawful alternatives – as an indispensable means of treating severe pain face the very "choice of evils" the necessity doctrine contemplates.[15]

III. THE COURT OF APPEALS CORRECTLY RESOLVED THE CONGRESSIONAL POWER QUESTION.

The Court need not go further here than deciding that Congress did not intend the CSA to reach seriously ill individuals whose possession of a drug is a matter of medical necessity. But if the Court concludes that the statute must be construed as having foreclosed all consideration of medical necessity – and proceeds to decide the broader question of Congress's power to enact such a law – it should uphold the judgment of the court of appeals that, as applied to Respondents, the statute is likely unconstitutional.

A. The Issue of Legislative Power Is Not Properly Decided in Isolation from the Affected Liberty Interest.

As explained above, the circumstances under which Respondents possess marijuana are fundamentally – constitutionally – different from those of a "recreational" user. Respondents' use of marijuana is in consultation with their

[15] Although Respondents raise necessity as a basis for granting injunctive relief, rather than as an affirmative defense, they satisfy the doctrine's elements. Indeed, the government has not attempted to challenge the gravity of Respondents' medical problems; the imminence of their need to obtain relief; the efficacy of marijuana in treating their symptoms, or the reasonableness of their prior efforts to secure relief through lawful means. The government's intent to take enforcement action against them is equally clear. *See* Pet. App. 6a (discussing prior seizure of Respondent Monson's medical marijuana supplies). In these circumstances, and given their already dire personal circumstances, it would be inequitable to require Respondents to await criminal prosecution before protecting themselves.

physicians, as a matter of self-preservation, because available conventional therapies have failed them. Moreover, it is compliant with their State's law, enacted pursuant to its core authority over matters of health and medical practice, recognizing the appropriateness of such use. *See Jacobson*, 197 U.S. at 38 ("the safety and the health of the people of Massachusetts are, in the first instance, for that commonwealth to guard and protect. They are matters that do not ordinarily concern the national government. So far as they can be reached by any government, they depend, primarily, upon such action as the state, in its wisdom, may take"); *United States v. Lopez*, 514 U.S. 549, 583 (1995) (Kennedy, J., concurring); *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002) (Kozinski, J., concurring).

The nub of the Government's submission is that the circumstances of Respondents' use are "irrelevant," Pet. Br. 29, to whether the statute's application is lawful under Article I. Because Congress has been held entitled to regulate conduct that "substantially affects" interstate commerce and because Congress has "determined" that possession of drugs belongs to a "class of activity" – also including distribution and manufacturing – that has such an effect, the Government argues, the Court must sustain the CSA's application to all those who fall within that "class." On this view, the liberty interests implicated by applying the statute against Respondents are beside the point – unless the Court is prepared to squarely hold that the application violates Due Process.

At the outset, this all-or-nothing theory of congressional power invites perverse results. Were it adopted, the more omnibus a statute's sweep – and the less care and attention Congress devoted to its specific applications – the more invulnerable to judicial scrutiny it would become. *See United States v. Stewart*, 348 F.3d 1132, 1141 (9th Cir. 2003). It would also be contrary to this Court's established approach to resolving congressional power questions. The Court has

repeatedly considered whether a particular application of a statute exceeded the Commerce power, *see, e.g., Jones v. United States*, 529 U.S. 848 (2000); *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241 (1964), and just last Term, rejected contentions that it is bound to decide wholesale whether a statute is a lawful exercise of congressional power. *See Tennessee v. Lane*, 124 S. Ct. 1978, 2003 (2004) ("nothing in our case law requires us to consider Title II [of the ADA], with its wide variety of applications, as an undifferentiated whole").

And it would require resolution of broad constitutional questions that are neither necessarily presented by the case nor necessary to decide. *See Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 217 (1995) (declining to reach Due Process question, when case could be resolved with respect to *federal* judicial power); *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) (declining to reach Tenth Amendment question, in absence of "clear statement" that Congress intended to reach State judges); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985) (similar, with respect to Eleventh Amendment).

In general, the Court does not determine the scope of a particular power in isolation from other pertinent constitutional interests. *See Printz v. United States*, 521 U.S. 898, 923 (1997) ("When a 'Law for carrying into Execution' the Commerce Clause violates the principle of state sovereignty * * * it is not a 'Law * * * proper for carrying into Execution the Commerce Clause.'"); *Lopez*, 514 U.S. at 560 & n.3; *Jones*, 529 U.S. at 857; *Hampton v. Mow Sun Wong*, 426 U.S. 88, 102-103, 112 (1976); *Kent v. Dulles*, 357 U.S. 116, 126-27 (1957); *Reid v. Covert*, 354 U.S. 1, 16, 21 (1957) (plurality opinion). As these cases establish, it matters greatly whether the application before the Court arises from the heartland of the power asserted or its periphery. *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 597 (1952) (Frankfurter, J., concurring) ("'[t]he great ordinances of the Constitution do not establish and divide fields of black and white'") (quoting *Springer v. Philippine Islands*,

277 U.S. 189, 209 (1928) (Holmes, J., dissenting)); *Dames & Moore v. Regan*, 453 U.S. 654, 668 (1981) (noting "spectrum" of federal executive power).[16]

This is true – indeed especially true – with respect to the relationship between congressional power and individual liberty. Far from being logically or legally independent, individual liberty and enumerated power are two sides of the same coin: the "Federal Government of enumerated powers" established in the Constitution "'was adopted by the Framers to ensure protection of our fundamental liberties.'" *Lopez*, 514 U.S. at 552 (quoting *Gregory*, 501 U.S. at 458). Indeed, the Framers treated the combination of the exclusive listing of the powers available to the government, judicial enforcement of those limitations, and scrutiny of the "necessity and propriety" of ancillary laws, as safeguards for the rights and liberties of the people. THE FEDERALIST NO. 84, at 515 (Rossiter ed., 1961) (describing the body of Constitution, as "in every rational sense, and to every useful purpose, A BILL OF RIGHTS"); D. SMITH, THE CONSTITUTION AND THE PRIDE OF REASON 45 (1998) (describing "[t]he enumerated powers strategy" as "the framers' principal method of protecting individual rights"); R. Barnett, *The Proper Scope of the Police Power*, 79 NOTRE DAME L. REV. 429, 435 (2004) (noting that, during period between ratification of the Constitution and adoption of Bill of Rights, almost all individual rights were "unenumerated").

B. Application of the CSA Against Gravely Ill Persons Possessing Marijuana for Therapeutic Purposes is Not a Lawful Means of Regulating Interstate Commerce.

The power claimed by the Government, to punish

[16] The Court likewise considers other individual rights, both those enumerated in the Bill of Rights and those not, in giving meaning to particular guarantees. *See, e.g., City of Chicago v. Morales*, 527 U.S. 41, 53 (1999) (plurality opinion); *Chavez v. Martinez*; *See generally Poe*, 367 U.S. at 543 (Harlan, J., dissenting) (asserting that rights are arrayed along a "rational continuum").

Respondents for possessing marijuana for personal, medical use, is not easily described as an exercise of the authority delegated by the Constitution: to regulate the "commerce among the states." U.S. CONST. art. I § 8, cl. 3. Possession of drugs is not itself "commerce," let alone "commerce among the states," and Respondents are not engaged in "economic activity" in any ordinary sense of that term – let alone in a commercial enterprise. *Compare Wickard v. Filburn*, 317 U.S. 111 (1942); *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937). Rather, application of the CSA is defended as an "essential part of a larger regulation," Pet. Br.10 (quoting *Lopez*, 514 U.S. at 561), *i.e.*, as a necessary and proper means of effectuating Congress's unquestioned power to regulate the interstate and international market in drugs. *See New York v. United States*, 505 U.S. 144, 158 (1992) (Court's "broad construction" of Interstate Commerce power "has of course been guided * * * by the Constitution's Necessary and Proper Clause"); *accord United States v. Darby*, 312 U.S. 100, 118 (1941).[17]

But such an application would be neither constitutionally "proper" nor "necessary." As to the former, as *Printz* acknowledged, a law is not "proper" unless consistent "with

[17]As *Lopez* makes clear, judicial deference to congressional regulation of economic actors – including their in-State activity – reflects a recognition that there is a single national market, *see Lopez*, 524 U.S. at 574 (Kennedy, J., concurring), over which Congress has a unique responsibility, *id.*; *see also H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 539 (1949) (describing premise of "dormant" Commerce jurisprudence).

Respondents do not challenge Congress's power to proscribe possession of marijuana for recreational use – an application that would touch on neither a recognized liberty interest nor States' traditional powers over health and welfare. Nor would invalidating this application call into question possession prohibitions that play a more than symbolic role in effectuating some national interest. *E.g.*, 18 U.S.C. § 175b (prohibiting certain persons from possessing biological agents or toxins); 42 U.S.C. § 2077(a) (prohibiting unauthorized possession of "special nuclear material"). Just as *Wickard* discarded conceptual distinctions between "production" and "commerce," it would be unsound to mint a categorical rule that in-State possession is beyond Congress's power to regulate.

principles of separation of powers, principles of federalism, and individual rights." G. Lawson & P. Granger, *The 'Proper' Scope of Federal Power: A Jurisdictional Interpretation of the Sweeping Clause*, 43 DUKE L.J. 267, 297-333 (1993).

The Government likewise fails to demonstrate that punishing gravely ill individuals for possession of a drug under circumstances of medical necessity is important, let alone necessary or "essential" to advancement of its legitimate interests in combating drug abuse or the evils associated with an interstate black markets in drugs. It points to no evidence that Congress, in enacting the CSA, even considered the plight of persons for whom a drug is medically indispensable, let alone determined that exempting such individuals would undercut the statutory scheme. On the contrary, the legislative history reveals that Congress's principal concern was with recreational drug abuse and addiction, particularly by young people. *See Oregon v. Ashcroft*, 368 F.3d 1118, 1128 (9th Cir. 2004) (citing H.R. Rep. No. 91-1444).

In fact, claims that prosecution for medically necessary possession is an "essential part"of a larger scheme blink reality. The Government trumpets the fact that 28.5 million individuals use marijuana annually, Pet.Br.32, yet the "fact sheet" it references, *see id.*, records that only 186 persons were convicted of violating the federal possession statute – and even that minuscule number must include many who (a) have no medical necessity claim whatsoever and/or (b) were charged with or at least suspected of serious distribution offenses. *Cf. Wickard.*[18]

The congressional findings accompanying the CSA, *see* 21 U.S.C. § 801, can not fill the void. Although the Government invokes (Br. 23-25) "findings" [1] that the "local * * *

[18]The Government's enforcement activities against Respondent Monson and other participants in California's Compassionate Use program are exceptional – presumably spurred by an intent to "prove a point" with respect to the federal government's purported power, as against California's effort to allow medicinal use of marijuana.

possession" of "controlled substances" will "contribute to swelling the interstate traffic in such substances," 21 U.S.C. § 801(4) and [2] that drugs possessed in one place "cannot be differentiated" from drugs that have been shipped across state lines, *id.* § 801(5), the latter "finding" does not reference "possession" at all, and the former is stated in compound terms, *i.e.*, including "local distribution and possession," so as to stack aggregation upon aggregation. In fact, individuals in Respondents' position are particularly unlikely to "swell" the interstate market: they have no interest in purchasing marijuana from traffickers – and the logical implication of their position (like any similar assertion of duress or self-defense) is that they will pursue the same course of conduct *even if* the shadow of criminal prosecution were not lifted. Finally, the "findings" imputed to Congress are not easily squared with the fact that California has determined that permitting possession by individuals in Respondents' situation does not even undercut its ongoing and energetic efforts to combat illegal *intra*state trafficking.

Under these circumstances – where the relationship to enumerated power is tenuous at best and the adverse effects on individual liberty are real and subsatantial – the Court would need no novel or highly restrictive theory of congressional power to sustain the conclusion that the application at issue is likely unconstitutional.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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DESCRIPTION OF *AMICI CURIAE*

Amicus Curiae **The Leukemia & Lymphoma Society** is the world's largest voluntary health organization dedicated to funding blood cancer research and providing education and services for blood cancer patients. Founded more than 50 years ago and headquartered in White Plains, New York, the Society operates through 63 chapters in the U.S. and additional branches in Canada. Its mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

Amicus Curiae **Pain Relief Network** ("PRN") is a network of pain patients, family members of people in pain, physicians, attorneys, and activists working toward a day when people in pain will be afforded the simple dignity and compassion due all ill Americans. PRN seeks to empower the over 50 million Americans living in untreated, disabling pain to advocate for improved care, and to strengthen the integrity of the doctor-patient relationship.

Amicus Curiae **California Medical Association** ("CMA") is a national association of physicians in California and is the largest state medical association in country. CMA's mission is to promote the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession. Founded in 1856 to set medical standards and create a forum for exchanging information and experience, CMA has become a leading advocate for improving the quality of health care, and has earned a national reputation for its advocacy on behalf of physicians and patients.

Amicus Curiae **AIDS Action Council** ("AIDS Action") is the Washington, D.C. representative of over 1,000 community-based organizations and the hundreds of thousands of persons living with HIV/AIDS whom these organizations serve. As the only national organization devoted entirely to federal advocacy on behalf of people living with HIV/AIDS, AIDS Action works

to ensure that effective national initiatives are undertaken for prevention, care, and research, and that policies are established that support the autonomy of people living with HIV/AIDS to make informed decisions about their health care needs.

Amicus Curiae **Compassion in Dying Federation** ("COMPASSION") is a national advocacy organization providing client service, legal advocacy and public education to improve pain and symptom management, increase patient empowerment and self-determination and expand end-of-life choices to include aid-in-dying for terminally ill, mentally competent adults. COMPASSION works toward improved care and expanded options at life's end, with goals of comprehensive, effective comfort care for every dying person, and legal and humane aid-in-dying if suffering is unbearable and cannot be relieved.

Amicus Curiae **End-of-Life Choices** is a national organization working to assure freedom of choice at the end of life. Founded as The Hemlock Society in 1980, the organization supports the rights of terminally ill, mentally competent adults to hasten death under careful safeguards. The organization supports legislation to maximize end-of-life options and provides education, information and advice about choices at the end. End-of-Life Choices believes that each individual is entitled to choose within the law both how to live and how to die.

Amicus Curiae **National Women's Health Network** ("the Network") is the only national public-interest membership organization devoted solely to women and health. Founded in 1974, the Network has influenced national policy as a women's voice dedicated to humane, responsive health care. The Network improves the health of all women by developing and promoting a critical analysis of health issues in order to affect policy and support consumer decision-making. The Network aspires to a health care system that is guided by social justice and reflects the needs of diverse women.

Amicus Curiae **Global Lawyers and Physicians** ("GLP") is a non-profit non-governmental organization that focuses on health and human rights issues. Founded in 1996 at the 50th Anniversary of the Nuremberg Doctors Trial, GLP was formed to reinvigorate the collaboration of the legal and medical/public health professions to protect the human rights and dignity of all persons, an important collaboration that gave rise to and inexorably shaped the Nuremberg Code. GLP believes that lawyers and physicians are better able to fulfill their sworn obligations to improving the well-being of their communities when members of these two professions work in partnership to promote both health and justice.

Amicus Curiae **AUTONOMY, Inc.** is a national disability rights organization representing the interests of individuals with disabilities who believe that people with disabilities should be able to exercise choices in all aspects of their lives. AUTONOMY, Inc. supports the right of people with terminal illnesses to have a full range of choices, including aggressive pain treatment and physician-assisted dying. The organization believes that people with disabilities who have struggled to maintain control over their own lives and bodies should maintain this decision-making autonomy throughout the process of living and dying.

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Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

ANGEL MCCLARY RAICH, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals For the Ninth Circuit

Brief For Lymphoma Foundation of America; HIV Medicine Association of the Infectious Diseases Society of America; American Medical Student Association; Dr. Barbara Roberts; and Irvin Rosenfeld As *Amici Curiae* In Support of Respondents

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INTEREST OF AMICI CURIAE*

Amici Curiae have personal or professional experience and expertise regarding medical, scientific and public health issues, and are united in their concern that this case be decided upon an accurate understanding of the medical and scientific facts.[1] There is overwhelming support for the legitimacy and efficacy – and sometimes unique therapeutic benefits – of herbal cannabis as medicine.

Amici are equally concerned that the Court understand that there are seriously ill patients who do not respond to or cannot tolerate conventional therapies. For these individuals, the art of medicine – the ability of health care professionals to work closely with them and fashion a treatment regimen tailored to their unique needs – assumes heightened importance.

SUMMARY OF ARGUMENT

A small but significant number of seriously ill patients who suffer from cancer, human immunodeficiency virus or Acquired Immune Deficiency, multiple sclerosis, epilepsy, chronic debilitating pain, spasticity, and other serious medical conditions, do not benefit from, or cannot tolerate the therapies of currently available conventional medicine. Many of these patients, like Respondents here, have found, together with their physicians, that marijuana effectively alleviates symptoms of their conditions and side effects caused by their primary treatments.

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*No counsel for any party authored any part of this brief. No person or entity, other than *Amici* and Savitt & Bruce LLP, made a monetary contribution toward submission of this brief, which is filed with parties' written consent.

[1] Descriptions of *Amici Curiae* are set forth in the Appendix to this brief.

The experiences of these patients and the observations of their physicians accord with the conclusions recently reached by blue ribbon government panels and in federally-funded, peer-reviewed scientific studies: that marijuana has therapeutic properties not replicated by other currently available medications. These studies have consistently found (1) that marijuana is an effective anti-inflammatory, analgesic, appetite-stimulating, antiemetic, and antispasmodic agent; (2) that its side effects are often less debilitating than those of drugs currently approved for treating the same ailments; and (3) that for some individuals it is the only meaningful option. For certain persons the medical use of marijuana can literally mean the difference between life and death. At a minimum, marijuana provides some seriously ill patients the gift of relative health and the ability to function as productive members of society.

Despite this convincing evidence, the federal government continues to impede individuals' access to marijuana for medical purposes – especially where those patients are cultivating or using it with the endorsement of their physician and entirely within states where its use is permitted under state law.[2]

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[2] To date a total of 26 States have recognized the medical benefits of cannabis in some form:

Nine States have enacted laws allowing medical use of cannabis. *See* Alaska Stat. §§ 11.71.090, 17.37.010 et seq. (Michie 2003); Cal. Health & Safety Code § 11362.5 (West Supp. 2004); Colo. Const. art. 18, § 4; Haw. Rev. Stat. Ann. § 329-121 et seq. (Michie Supp. 2003); Me. Rev. Stat. Ann. tit. 22, § 2383-B (West 2004); Nev. Rev. Stat. Ann. § 453A.200 (Michie Supp. 2003); Or. Rev. Stat. §§ 475.300-.346 (2003); Vt. Stat. Ann. tit. 18 § 4272 et seq. (2004); Wash. Rev. Code Ann. §§ 69.51.010-.080 (West 2004).

Five additional States have enacted laws recognizing the therapeutic benefits of cannabis but authorize use only by prescription, *see* Ariz. Rev. Stat. § 13-3412.01 (West 2004); La. Rev. Stat. Ann. § 40:1201 (West 2003); N.H. Rev. Stat. Ann. § 318-B:10(VI) (2003); Va. Code Ann. § 18.2-251.1 (Michie 2003), or classify cannabis as having "currently

Let it be clear: if the ruling of the Court of Appeals is not upheld, patients with debilitating, often life-threatening conditions not only will be deprived of an important and effective treatment option, they will be condemned to real and avoidable suffering.

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accepted medical uses," *see* Iowa Code §§ 124.205, 124.206(7)(a) (West 2003).

Two additional States have passed resolutions urging the federal government to allow the medical use of cannabis. *See* Mo. Sen. Con. Res. 14 (1994); N.M. Sen. Memorial 42 (1982), *available at* http://www.sumeria.net/nmcu/memorial.html.

Seven additional States have enacted laws recognizing cannabis's potential medical benefits for persons suffering from conditions including cancer, nausea, and glaucoma, and establishing therapeutic research programs for the benefit of such persons. *See* Ala. Code § 20-2-111 et seq. (1979); Ga. Code Ann. §§ 43-34-120 et seq. (1980); 720 Ill. Comp. Stat. 550/11 (1971); Mass. Gen. Law Sch. 94D, §§ 1-3 (1991); N.Y. Pub. Health Law §§ 3328(4), 3397-a to 3397-f (1980); Minn. Stat. § 152.21 (1980); S.C. Code Ann. §§ 44-53-620 et seq. (1980).

The courts of two additional States have allowed cannabis patients to raise a necessity defense to charges of marijuana possession. *See Sowell v. State*, 738 So.2d 333, 334 (Fla. Dist. Ct. App. 1998); *State v. Hastings*, 801 P.2d 563, 565 (Idaho 1990). A third State recently limited the penalty for possessing cannabis for medical purposes to a $100 fine. *See* Md. Code Ann., Crim. Law art. 5-601(c)(3).

This State legislation reflects strong popular support for medical use of cannabis in appropriate circumstances. See, e.g., Coleen McMurray, *Medicinal Marijuana: Is It What the Doctor Ordered?*, Gallup Poll Tuesday Briefing (Dec. 16, 2003) (75% of Americans support allowing physicians to prescribe cannabis to patients); The Polling Report, Inc., *Illegal Drugs*, http://www.pollingreport.com/drugs.htm (last visited October 11, 2004) (CNN/Time poll: 80 percent of Americans favor allowing adults to use cannabis for medical purposes on a physician's recommendation).

ARGUMENT

I. RELIABLE RESEARCH AND CLINICAL EXPERIENCE PROVIDE A SOUND BASIS FOR THE MEDICAL USE OF MARIJUANA BY CERTAIN SERIOUSLY ILL PATIENTS

Clinical experience and a growing body of medical research confirm that for a small but significant number of patients, marijuana serves as the *only* effective medicine for suppressing nausea, stimulating appetite, or relieving pain. *See e.g. Conant v. Walters*, 309 F.3d 629, 640-43 (9th Cir. 2002) (Kozinski, J., concurring), *cert. denied*, 124 S. Ct. 387 (2003) (summarizing the medical evidence supporting limited medical use of marijuana). Indeed, the scientific literature – and the highly respected research panels from the United States and Great Britain – make clear that there is widespread agreement that cannabis is effective in alleviating the symptoms of many patients who have not obtained relief from conventional treatments.[3]

A. A U.S. Government Panel Concluded That Marijuana Is Effective And Medically Beneficial

In 1997, largely in response to the passage of California's Compassionate Use Act[4], the White House

[3] In this vein, it should be noted that of the several briefs *amici curiae* filed on behalf of Petitioner, only one brief takes strong issue with notion that herbal cannabis can play a therapeutic role of herbal cannabis, *See Brief Amici Curiae* of Drug Free America Foundation, *et al.*, while the amicus brief submitted by nationally renowned physicians Robert DuPont and Herbert Kleber acknowledges the widespread and legitimate medical use of cannabis by patients residing in Canada and the Netherlands. *See Brief Amici Curiae* of Robert DuPont, M.D., *et al.*, at 26-27.

[4] Cal. Health & Safety Code § 11362.5 (West Suppl. 2001) (available online at http://www.leginfo.ca.gov/calaw.html).

Office of National Drug Control Policy commissioned the National Institute of Medicine of the National Academy of Sciences ("IOM")[5] to undertake an extensive review of the scientific evidence of the therapeutic applications of cannabis.[6] The IOM was tasked with assessing the current scientific findings concerning medical marijuana. In accomplishing its task, the IOM reviewed the scientific bases identifying the active ingredients of marijuana, how those ingredients act on human and animal physiology, and clinical experiments evaluating the efficacy of marijuana and several of its active agents. *Institute of Medicine Marijuana and Medicine: Assessing the Science Base*, (Janet E. Joy, et al, eds., National Academy Press 1999) ("IOM" Report), at 9.

The result of an exhaustive year-long study, which included scientific workshops, analysis of relevant scientific literature, and extensive consultation with biomedical and social scientists, was the 250-plus-page IOM Report, which concluded that "[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation." IOM report at 15, 179.

The IOM acknowledged that marijuana currently provides the only alternative for certain people for whom approved medicines are ineffective and emphasized the desirability of further research into the effects of cannabinoids and the development of systems by which the active ingredients of marijuana can be delivered to patients in a dose-controlled, smoke-free manner. IOM Report at 10-11, 179. As a result, it is not surprising that the IOM

[5] The IOM was chartered in 1970 by the National Academy of Sciences ("NAS") to bring professionals in different disciplines together to examine policy matters pertaining to the health of the nation. The IOM furthers NAS's responsibility to advise the federal government on such issues pursuant to an 1863 congressional charter.

[6] The complete IOM report is available at http://www.nap.edu/books/0309071550/html.

conditionally endorsed medical marijuana.[7] Additional examples of specific findings and studies relied on by the IOM are identified in Section II below.

B. Great Britain's House of Lords Concluded that Marijuana Holds Medical Benefits for Certain Seriously Ill Patients

While the IOM was conducting its evaluation, Great Britain's House of Lords was also conducting hearings and taking testimony from leading researchers, clinicians and patients regarding the medical benefits and drawbacks of cannabis.[8] The findings and recommendations of the Lords Report closely parallel those of the IOM. The House of Lords concluded that "cannabis almost certainly does have genuine medical applications, especially in treating the painful muscular spasms and other symptoms of MS and in the control of other forms of pain. Lords Report § 8.2 at 41. The House of Lords called for additional scientific studies into marijuana's medical value as well as identifying alternative modes of administration which would retain the benefit of rapid absorption offered by smoking, while minimizing any adverse effects. Lord Report §§ 8.1-8.4, at 41.

Given the state of current medical knowledge and anecdotal evidence attesting to the efficacy of marijuana, the House of Lords concluded that the government should act immediately 'to allow doctors to prescribe an appropriate preparation of cannabis, albeit as unlicensed medicine."[9]

C. An Administrative Law Judge Likewise Concluded that Marijuana has Accepted Medical Uses

In the late 1980's, the United States Department of Justice referred petitions seeking removal of marijuana from the list of Schedule I substances under the Controlled Substances Act,[10] to Francis L. Young, and Administrative Law Judge in the Drug Enforcement Administration. In September 1988, after more than two years of evidentiary hearings and other proceedings, Judge Young rendered an *Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge in the Matter of Marijuana Rescheduling Petition*, Docket No. 86-22 (Dep't Justice D.E.A., Sept. 6, 1988) (hereinafter, "ALJ Opinion").[11] Judge Young found that the

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[7] Specifically, the IOM Report suggested that:

> Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms...must meet the following conditions: [i] failure of all approved medications to provide relief has been documented, [ii] the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs, [iii] such treatment is administered under medical supervision in a matter that allows for assessment of treatment effectiveness, and [iv] involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

IOM Report at 179. While the IOM's statement ostensibly would limit the use of marijuana to six months' duration, in the context of the full report, it is apparent that the IOM does not urge the automatic termination of treatment at the arbitrary date, but rather recommends that patients' marijuana use be reevaluated on at least a semiannual basis. The authors' reluctance to approve the longer-term use of cannabis was based primarily on their concern about the possible pulmonary risks posed by smoking marijuana.

[8] Select Committee on Science and Technology, House of Lords, Sess. 1997-98, 9th Report, Cannabis: The Scientific and Medical Evidence (Nov. 4, 1998), available at http://www.publications.parliament.uk/pa/ld199798/ldselect/ldsctech/151/15101.htm ("Lord Report").

[9] Lord Report § 8.6 at 41. The United Kingdom, unlike the United States, allows physicians to prescribe an unapproved medicine to a particular patient, so long as certain conditions are followed. Se generally, Lord Report at 22.

[10] See 21 U.S.C. § 812.

[11] The complete text of Judge Young's opinion is available at http://www.druglibrary.org/schaffer/library/studies/YOUNG/index.html.

facts established that marijuana has an "accepted medical use" for treatment of (a) nausea resulting from chemotherapy, (b) spasticity resulting from multiple sclerosis and other causes, and (c) hyperparathyroidism.[12]

Additionally, the ALJ Opinion held that "there is accepted safety for use of marijuana under medical supervision." ALJ Opinion at 66. In particular, Judge Young noted that "[t]here was no record in the extensive medical literature describing a proven, documented cannabis-induced fatality," and that marijuana has an estimated LD-50 rating[13] of between 1:20,0000 and 1:40,0000. ALJ Opinion at 56-57. In lay terms, a smoker would have to consume 20,000 to 40,000 times as much marijuana as is contained in one marijuana cigarette (approximately 1,500 pounds) in fifteen minutes to induce a lethal response. ALJ Opinion at 57.

Judge Young concluded:

> [t]he evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA [the Drug Enforcement Administration] to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.

ALJ Opinion at 68. The Administrator of the DEA rejected the findings and recommendations of Judge Young, asserting

[12] Hyperparathyroidism is a condition causing increased calcium in the blood. Symptoms include nausea, vomiting, abdominal pain, skeletal pain, and weakened skeletal structure. See http://familydoctor.org, American Academy of Family Physicians, 2000.

[13] An LD-50 or LD-50 value is the amount of material that it takes to kill 50% of a test group in one dose. LD-50's are extrapolated for human dosage from animal studies.

that there was no scientific evidence showing that marijuana was better than other approved drugs for any specific medical condition, *see* 54 Fed. Reg. 53767 (Dec. 29, 1989). However, unlike Judge Young's findings, the DEA's conclusions lacked evidentiary support.

D. After Evaluating the Medical Evidence, Canada Now Permits Medical Marijuana

After a thorough review of medical evidence similar to that considered by the IOM and House of Lords, Canada adopted "Marihuanna Medical Access Regulations" on July 30, 2001.[14] These Regulations permit the possession and production of marijuana for medical purposes. The Regulations were developed by Health Canada, the federal agency responsible for helping the people of Canada maintain and improve their health. The agency promulgated the regulations after it had conducted its own survey of the scientific evidence regarding the therapeutic value of smoked marijuana.[15] While Health Canada's official position mirrors that of the American Medical Association (i.e.; that scientific

[14] Marihuanna Medical Access Regulations, SOR/2001-227, § 2 et seq. (June 14, 2001) (Can.), available at http://www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm. These regulations resulted from a year-long effort to address several issues revolving around the Ontario Court of Appeal's decision that the then existing exemptions to the Controlled Drugs and Substances Act were unconstitutional. See *R. v. Parker*, 2000 W.C.B.J. LEXIS 10970, 75 C.R.R. (2d) 233, 47 W.C.B. (2d) 116 (July 31, 2000) (available at http://www.ontariocourts.on.ca/decisions/2000/july/parker.htm);
Regulatory Impact Analysis Statement of the Marihuanna Medical Access Regulations amending the Narcotic Control Regulations (7/4/20021), available at http://ww.hc-sc.gc.ca/hecs-secs/ocma/index.htm.

[15] As of September 2004, 757 Canadians were currently allowed to possess marihuana for medical purposes, and 553 were authorized to persons are currently allowed to cultivate/produce marihuana for medical purposes. Health Canada, Office of Cannabis Medical Access. (http://www.hc-sc.gc.ca/hecssesc/ocma/stats/2004/sept/stats_sept-04.htm) (last visited October 11, 2004).

studies supporting the safety and efficacy of marijuana for therapeutic claims are, to date, inconclusive), it nevertheless recognized the potential value of marijuana for a determined group of patients. For that reason, the agency developed regulations to allow certain persons the ability to possess and cultivate marijuana for medical use.[16]

Consistent with the IOM, the House of Lords, and the weight of scientific evidence and clinical experiences attesting to marijuana's efficacy, Canada's law permits doctors to recommend and prescribe medical marijuana to certain persons who are suffering from severe pain, muscle spasms, anorexia, weight loss, and nausea, and who have not found relief from conventional therapies.[17]

II. MARIJUANA HAS RECOGNIZED ANALGESIC, ANTIEMETIC, ANTI-INFLAMMATORY, AND APPETITE-ENHANCING PROPERTIES

A. Marijuana Is An Effective Pain Killer

Patients with various pain syndromes claim significant relief from marijuana.[18] In fact, researchers have reported 18 of 23 patients suffering from intractable pain experienced significant pain reduction from cannabis extract that was sprayed under their tongue.[19] The validity of this

[16] Health Canada recently announced its plans to make government-certified marijuana available in local pharmacies to authorized patients, beginning with a pilot project being organized in British Columbia. Associated Press, *Canada Plans Pharmacy Marijuana Project* (March 21, 2004).

[17] Office of Cannabis Medical Access, *Medical Access to Marijuana – How the Regulations Work, available at* http://www.hc-sc.gc.ca/hecs-sesc/ocma/bckdr_1-0601.htm.

[18] *See, e.g.*, Lord Report §§ 5.26-5.30 at 24; IOM Report at 53-56.

[19] Clive Cookson, *High Hopes for Cannabis to Relieve Pain: British Association Science Festival in Glasgow*, Financial Times, Sept. 4, 2001,

finding is corroborated by studies in which cannabinoids have been shown to be effective analgesics in animal pain models.[20] This is particularly true for patients suffering from neuropathic pain.

Neuropathic pain is a symptom commonly associated with a variety of illnesses or conditions, including metastic cancer, HIV/AIDS, multiple sclerosis (MS), and diabetes, it can also be a side effect of the recommended treatments for various conditions. [21] Neuropathic pain in HIV/AIDS can be caused by HIV infection, or by the drugs used to treat it.[22] Currently approved treatments have substantial limitations in their effectiveness for relieving neuropathic pain. The absence of more effective and acceptable treatments for neuropathic pain is particularly problematic for certain HIV patients in which there are no good alternatives to antivirals

at National News pg. 4, *available at* http://news.ft.com/ft/gx.cgi/ftc?pagename=View&cid=FT3WWJOM6RC&live=true&query=cannabis

[20] *See, e.g.*, William J. Martin, *Basic Mechanisms of Cannabinoid-Induced Analgesia*, IASP Newsletter (International Association of the Study of Pain) Summer 1999, at 89 ("There is now unequivocal evidence that cannabinoids are antinociceptive [capable of blocking the appreciation or transmission of pain] in animal models of acute pain").

[21] Many of the reverse transcriptase and protease inhibitors commonly prescribed as part of the "AIDS cocktail" cause side effects including peripheral neuropathy, nausea, and vomiting. *See e.g.*, Physician's Desk Reference 889 (Didanosine), 895 (Stavudine) (54th ed. 2000).

[22] *See, e.g.*, David M. Simpson et al., *Selected Neurologic manifestations of HIV Infection: Dementia and Peripheral Neuropathy, improving the Management of HIV Disease*, Dec. 1999; Nathalie Do Quang-Cantagtrel et al., *Opioid Substitution to Improve the Effectiveness of Chronic Noncancer Pain Control: A Chart review*, 90 Anesthesia & Analgesia 933 (2000) (reporting opioid analgesics are effective for only 36% of patients, ineffective for 34% and intolerable for 30% of patients); Neurologic AIDS Research Consortium, *Peripheral Neuropathy (2004), available at* http://www.neuro.wustl.edu/narc/peri-neuropathy.html ("Treatment of neuropathic pain…is notoriously difficult. Even narcotics may not fully relieve [it].").

causing neuropathic pain, either due to drug resistance or other side effects from alternative drugs.[23]

B. Marijuana Is Effective In Treating Nausea, Anorexia And Wasting

Nausea, anorexia, and wasting are common symptoms of many cancers and HIV/AIDS. These symptoms are also the common adverse side effects of chemotherapy and other aggressive therapies used to treat those diseases and associated pain.[24] While other antiemetics may be available, not all patients respond to these therapies.[25] IOM at 153, 154.

Marijuana can provide critical relief for persons suffering from acute chronic nausea and vomiting who do not respond to conventional therapies.[26] As the Institute of Medicine explains,

[23] *Id.*

[24] The nausea-inducing properties of opioid analgesics used to treat pain are uncontroverted. *See, e.g.*, Am. Med. Ass'n, Encyclopedia of Medicine 98 (Charles B. Clayman ed., 1989) ("Nausea [and] vomiting ... may occur with narcotic analgesic drugs."); The Merck Manual of Diagnosis and Therapy (Robert Berkow ed., 17th ed. 1999) (same). *See also*, IOM Report at 151 (observing that patients receiving aggressive chemotherapy have "a 20-30% likelihood of experiencing acute emesis").

[25] *See, e.g.*, IOM Report at 157 ("Few therapies have proved successful in treatment of the AIDS wasting syndrome.").

[26] A New York State-sponsored study examined the effects of herbal cannabis on cancer chemotherapy patients who were unresponsive to standard antiemetics and found that 78% responded positively to cannabis. Vincent Vinciguerra et al., *Inhalation Marijuana as an antiematic for cancer chemotherapy*, N.Y.S.J. Med. 525 (Oct. 1988). Several other states have undertaken similar trials with similar results. *See generally* Richard E. Musty & Rita Rossi, *Effects of Smoked Cannabis and Oral Delta-0-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials*, 1 J. Cannabis Therapeutics 29 (2001). *See also* Lords Report § 5.12, at 21 (finding cannabis effective in alleviating acute nausea and vomiting).

> It is possible that the harmful effects of smoking marijuana for a limited period of time might be outweighed by the antiemetic benefits of marijuana, at least for patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis. Such patients should be evaluated on a case-by-case basis and treated under close medical supervision.

Id. at 154. As the Institute of Medicine noted, "[t]he critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but whether some group patients might obtain added or better relief from marijuana or cannabinoid drugs." IOM Report at 153. The IOM unequivocally concluded that there is indeed a group of patients to whom marijuana offers relief and that even the potentially harmful effects of smoking marijuana may be outweighed by the benefit provided.

Similarly, marijuana affords essential relief to patients suffering from anorexia and wasting syndromes for whom no other medications have been effective.[27]

C. Marijuana Is Effective In Treating Muscle Spasticity

Current treatments for painful muscle spasms, commonly associated with multiple sclerosis ("MS") and spinal cord injuries, have only limited effectiveness, and their use is complicated by various adverse side effects. IOM Report at 164. A growing body of clinical and preclinical

[27] IOM Report at 157 ("[Cannabinoids] could ... be beneficial for a variety of effects, such as increased appetite, while reducing the nausea and vomiting caused by protease inhibitors and the pain and anxiety associated with AIDS."); Lords Report § 5.15, at 22 (noting cannabis can counteract anorexia and wasting).

literature demonstrates that cannabinoids are effective in controlling the debilitating symptoms of MS.[28]

Conventional treatments have limited effectiveness for bladder dysfunction and pain associated with MS.[29] Marijuana, however, has been shown to be effective in alleviating these problems. Lord Report §§ 5.19-5.23, at 23. In addition, a survey of British and American MS patients reports that a significant majority experienced substantial improvements in controlling muscle spasticity and pain after ingesting marijuana.[30] An extensive neurological study likewise found that herbal cannabis provided relief from both muscle spasms and ataxia (loss of coordination), a multiple benefit not achieved by any other currently available medications.[31]

D. Marijuana Is Effective In Controlling Seizures

Clinical experience and emerging research also indicate that marijuana can help control epileptic seizures.[32] Cannabidiol (CBD), one of the primary (and

[28] *See* David Baker, et al., *Cannabinoids control spasticity and tremor in a multiple sclerosis model*, 404 Nature 117 (Mar. 2, 2000); Lords Report §§ 5.19 – 5.23, at 23. *See also* Mitch Earleywine, *Understanding Marijuana* 188 (Oxford University Press 2002).

[29] *See* Institute of Medicine, *Multiple Sclerosis: Current Status and Strategies for the Future* 143, 171 (Janet E. Joy & Richard B. Johnston, eds. 2001), *available at* http://www.nap.edu/books/0309072859/html.

[30] Paul Consroe *et al.*, *The Perceived Effects of Smoked Cannabis on Patients with Multiple Sclerosis*, 38 European Neurology 44 (1997) (reporting 96.5% of subjects with symptoms experienced lessened nighttime spasticity and 95.1% experienced reduced muscle pain, and greater than 70% of subjects reported decreased night leg pain, depression, tremor, anxiety, spasms on walking, leg weakness, trunk numbness, and facial pain).

[31] H.M. Meinck et al., *Effect of Cannabinoids on Spasticity and Ataxia in Multiple Sclerosis*, 236 J. Neurology 120 (1989).

[32] Lords Report § 5.31, at 24.

nonpsyhcoactive) cannabinoids present in the cannabis plant, appears to be of particularly beneficial, allowing patients who ingest it at certain times to avoid seizure activity. Some epileptics who cannot tolerate other antiseizure medications have been able to use marijuana to successfully control their seizures, without experiencing debilitating side effects.[33]

E. The Side Effects Of Marijuana Are No More Severe And Often Less Severe Than The Side Effects Of Many Currently Sanctioned Medications

The IOM examined the various potential harms associated with the medical use of marijuana and determined that "the acute side effects of marijuana use are within the risks tolerated for many medications," although its long-term chronic use may implicate concerns related to smoking. IOM Report at 126. Indeed, marijuana is considered to have a very wide margin of safety.[34] In contrast, many of the commonly prescribed antiemetic medications cause moderate to severe side effects in patients, including confusion and marked sedation.[35] The side effects of marijuana can be summarized as follows:

[33] *See* Jomar M. Cunha, *Chronic Administration of Cannabidiol to Healthy Volunteers and Epileptic Patients*, 21 Pharmacology 175 (1980); *R. v. Parker*, *supra* note 14, at *3 (holding that epileptic who suffered "frequent serious and potentially life-threatening seizures" and for whom surgery and conventional medications were unsuccessful is entitled to take marijuana to control seizures notwithstanding the prohibition of medicinal marijuana use under Canadian drug control statutes at that time).

[34] *See R. v. Parker*, *supra* note 14 at *48-49 (noting wide margin of safety of, and no evidence of overdose fatality from cannabis); ALJ Opinion at 56-60. *See also* Earleywine, Understanding Marijuana, supra note 28 at 186-189 & 195.

[35] *See, e.g.*, Physician's Desk Reference 3293, 3050 (54th ed. 2000) (side effects of Phenergan include sedation, confusion, and occasional nausea; side effects of Thorazine include suppression of cough reflex, drowsiness,

- Marijuana shows no indication of having immunosuppressant effect.[36]

- The ingestion of marijuana raises the heart rate, but there is no evidence that this increase poses a risk of cardiac arrest in patients who do not have pre-existing heart problems or who are otherwise in a high-risk group.[37]

- Some studies have suggested that marijuana smokers, like tobacco smokers, have a greater number of cellular and molecular abnormalities in the bronchial epithelium cells than nonsmokers, and that these changes are associated with an increased cancer risk.[38] However, "[t]here is conflicting evidence on whether regular marijuana use harms the small airways of the lungs," and it is therefore unlikely that the pulmonary side effects from smoking marijuana will be more severe than the side effects from smoking tobacco, a widely available and government-sanctioned drug.[39] Moreover, particularly for persons

fainting and dizziness upon initial dosing, and occasional muscle spasms).

[36] *See* IOM Report at 110; D. Abrams, *Short Term Effects of Cannabinoids on HIV-1 Infection*, Annals of Internal Medicine August 19, 2003; at 258-259; D. Abrams, *Short Term Effects of Cannabinoids on HIV-1 Viral Load*, presented at the 13th International AIDS Conference, Durban, South Africa (July 2000) (the use of cannabis does not adversely affect the immune system of HIV patients taking antiretroviral therapies).

[37] *See* IOM Report at 121.

[38] Sanford H. Barsky *et al.*, *Histopathologic and Molecular Alterations in Bronchial Epithelium in Habitual Smokers of Marijuana, Cocaine, and/or Tobacco*, 90 J. Nat'l Cancer Inst. 1198 (1998).

[39] IOM Report at 115. It is uncertain whether smoking cannabis, particularly for patients who may only consume enough to mitigate their symptoms, can actually cause pulmonary harm, such as chronic obstructive pulmonary disease (COPD) or lung cancer. *See* Lynn Zimmer and John P. Morgan, Marijuana Myths, Marijuana Facts 113-15 (Lindesmith Center 1997); Stephen Sidney *et al.*, *Marijuana use and*

suffering terminal illnesses, any such potential side effect is of little significance.

- The ability to titrate the dose of cannabinoids permits marijuana smokers to limit their intake of the drug to a dose that minimizes the impairment of their mental functioning.[40]

- The prescribed use of many common medications for pain, anxiety, and even hypertension may produce tolerance and physiological dependence; while some patients who use marijuana on a chronic basis may develop mild physiological dependence and experience withdrawal symptoms, these are minor in comparison to those associated with other medications routinely administered to treat serious illness.[41]

III. SYNTHETIC THC IS APPROVED AS A PRESCRIPTION DRUG, BUT OFTEN IS NOT AS EFFECTIVE, DESIRABLE, OR SAFE AS SMOKING MARIJUANA

Marinol – the brand name of dronabinol and a synthetic isomer of THC – is not a satisfactory treatment

cancer incidence, 8 Cancer Cause & Control 722 (1997).

[40] *See infra* Lords Evidence, note 44 at 178.

[41] IOM Report at 90-91 (stating that compared to tobacco and alcohol, dependence on cannabis is relatively rare and that marijuana withdrawal "has been reported only in a group of adolescents in treatment for substance abuse problems and in a research setting where subjects were given marijuana or THC daily [and then precipitously withdrawn from it]." Even then, the withdrawal symptoms "were short lived" and "[i]n four days they had abated.") (*citing* T.J. Crowley, *et al.*, *Cannabis dependence, withdrawal, and reinforcing effects among adolescents with conduct symptoms and substance use disorders*, 50 Drug & Alcohol Dependence 27-37 (1998)); M. Haney, *et al.*, *Abstinence symptoms following smoked marijuana in humans*, 141 Psychopharmacology 395-404 (1999); R. Jones, *et al.*, *Clinical studies of tolerance and dependence*, 282 Annals of New York Academy of Sciences 221-239).

alternative for many patients for at least four reasons. First, while Marinol is approved by the Food and Drug administration to treat nausea and vomiting associated with cancer chemotherapy and anorexia associated with weight loss in patients with AIDS, its pill form sometimes undermines its effectiveness. For instance, paradoxically, the pill is often regurgitated before it can suppress vomiting. 64 Fed. Reg. 35,928 (1999). Moreover, many patients suffering from the symptoms for which Marinol is approved, are unable to swallow the drug. As a result, patients often are unable to ingest a sufficient quantity of the drug to benefit from its effects. *See e.g.* ALJ Opinion at 11. In contrast, neither vomiting nor the inability to swallow diminishes the efficacy of THC delivery by smoking marijuana.

Second, unlike smoked marijuana, Marinol delays relief. Marinol is ingested – while the active ingredients in smoked marijuana are inhaled – patients in need of immediate relief must often suffer for an extended period of time before Marinol takes effect. By contrast, smoking marijuana is a more efficient delivery mechanism that provides the blood stream with the drug's therapeutic benefits, almost instantaneously, resulting in prompt relief for patients:

> Smoking . . . delivers rapid drug effect, whereas the THC capsule takes effect slowly, and its results are variable. There are many symptoms for which a quick-acting drug is ideal such as pain, nausea and vomiting.

Opening Statement of Stanley J. Watson, Jr., Institute of Medicine News Conference Marijuana and Medicine: Assessing the Science Base (Mar. 17, 1999).[42]

[42] The complete text is available at http://www.4.nationalacademics.org (search for "Watson and Marijuana").

Third, smoking marijuana has less debilitating psychoactive side effects than Marinol. After being swallowed, Marinol is delivered first to the stomach and then to the liver where it is metabolized into 11-hyddroxy-deta-THC. This metabolite is three times more psychoactive than THC delivered to the lungs by smoked cannabis. IOM Report at 36.[43] Therefore, not only do patients on Marinol suffer a prolonged wait for relief, but they also often experience harsh psychoactive side effects which they are then unable to mitigate from ingesting a full dose of the THC. By contrast, patients who smoke marijuana can regulate their dose of THC, achieving the desired therapeutic effect without experiencing the same intensity of psychoactive side effects.

> [S]moking . . . is actually a very good route of administration, in some ways; it is very effective, there is a very rapid absorption, and the patients have a great deal of control over how much they take. They learn to titrate.[44]

Fourth, marijuana contains other effective active ingredients not contained in Marinol. Marinol is composed of only a single compound, THC. By contrast, marijuana is a complex botanical substance, containing over 400 components and approximately 66 cannabinoids, which fall

[43] Citing Razdan, R., *Structure-activity relationships in cannabinoids*, 38 Pharmacology Rev. 75-149 (1986).

[44] Select Committee on Science and Technology, the House of Lords, Sess. 1997-98, Cannabis: The Scientific and Medical Evidence: Evidence (Nov. 4 1998) ("Lords Evidence"). As an alternative to smoking, the therapeutic components of the cannabis plant can be inhaled using vaporizer devices. Vaporizers heat cannabis to 150-200 degrees Centigrade, evaporating the cannabinoids and other volatile oils. This temperature is below the burning point of combustible plant material, so smoke is not generated. This technology has been available for over 20 years. John M. McPartland & Patty L. Pruitt, *Medical Marijuana and its Use by the Immunocompromised*, 3 Alternative Therapies 39, 43 (1997).

into 10 groups of closely related cannabinoids. IOM Report at 24. The main cannabinoids include delta9-THC, delta8-THC, Cannabidiol ("CBD"), cannabinol, cannabichromene, and cannabigerol. IOM Report at 24-25. Several of these cannabinoids – not just THC – have therapeutic applications, either alone or in combination with others.

> Herbal cannabis contains a mixture of active compounds. It is too early to be certain if the therapeutic action [of cannabis] is limited to one compound . . . Cannabis may contain a synergistic mixture of active compounds. This is particularly likely now that we know there are at least two receptor specified loci of action.[45]

Lords Evidence at 32. For example, CBD, which is not psychoactive, has been shown to have potential neuroprotective and anti-inflammatory uses.[46]

So while a viable option for many patients, Marinol's limitations make the "choice" of using it illusory in fact for some of the most seriously ill patients.

[45] *See also* John M. McPartland & Patty L. Pruitt, *Side Effects of Pharmaceuticals Not Elicited by Comparable Herbal Medicines: The Case of Tetrahydrocannabinol and Marijuana*, 5 Alternative Therapies 57, 60 (1999).

[46] *See* A.J. Hampson et al., *Cannabidiol and (-)delta-9-tetrahydrocannabinol are neuroprotective antioxidants [sic]*, 95 Proceedings of the National Academy of Sciences 8268 (July 1998) (addressing neuroprotection use); A.M. Malfait, et al., *The nonpsychoactive cannabis constituent cannabidiol is an oral anti-arthritic therapeutic in murine collagen-induced arthritis*, 97 Proceedings of the National Academy of Science 9561 (Aug. 2000) (addressing anti-inflammatory/anti-arthritic uses). These articles are available at http://www.pnas.org/all.shtml (search for the desired author).

IV. THE PERSONAL EXPERIENCES OF BOTH MEDICAL PROVIDERS AND PATIENTS SUPPORT SCIENTIFIC AND GOVERNMENT FINDINGS THAT MARIJUANA CAN BE AN EFFECTIVE THERAPEUTIC

Support for the medicinal value of marijuana is widespread. In a 1991 Harvard survey of more than 2400 oncologists, over 40% of respondents had recommended the use of marijuana for the control of nausea and vomiting to at least one cancer patient. Almost half considered cannabis to be therapeutically useful and would prescribe it if it was lawful to do so.[47] The AMA's Council on Scientific Affairs, since at least 1997, has cautiously acknowledged the potential medical efficacy of marijuana and called for additional

> [a]dequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficiency and the application of such results to the understanding and treatment of disease.[48]

In addition, many physicians find that marijuana's efficacy rivals or surpasses that of other antiemetic drugs for certain patients.[49] When comparing marijuana to Marinol,

[47] *See* Richard E. Doblin & Mark A.R. Kleiman; *Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes*, 9 J. Clin. Oncol. 1314-1319 (1991).

[48] Report 10 of the Council on Scientific Affairs (I-97), *Medical Marijuana*28, available at http://www.ama-assn.org/ama/pub/article/2036-4299.html. The recommendation for additional research was affirmed at the AMA's 2001 Annual Meeting. Report 6 of the Council on Scientific Affairs (A-01), *Medical Marijuana*, available at http://www.ama-assn.org/ama/pub/article/2036-6124.html.

[49] *See, e.g.*, Sallan, S.E., Zinberg, N.E. (1975). *Antiemetic effects of delta-9-tetrahydrocannabinol in patients receiving cancer chemotherapy*. New England Journal of Medicine, 293, 795-797 cited in Earleywine, M.,

44% of oncologists believed that smoked marijuana was more effective.[50]

While many physicians who recommended marijuana do not consider it the first line of defense against the symptoms or side effects of their patients' serious illnesses, they do recognize it as a valuable medication for those patients who cannot tolerate or who do not respond well to conventional medications.

CONCLUSION

Convincing scientific evidence and clinical experience demonstrate that smoking marijuana provides medical benefits that are not replicated by synthesized drugs. Recent government sponsored studies in the United States and Great Britain confirm this conclusion. Canada has now approved usage of medical marijuana. In addition, the collective weight of scientific studies, patients' personal experiences, physicians' clinical successes, and government-sponsored studies provides a convincing basis for the medical use of cannabis by certain patients. For the foregoing reasons, the decision of the Court of Appeals should be affirmed.

Respectfully submitted,

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[50] *See* Doblin, *supra*, note 47.

APPENDIX

Description of Amici:

Amicus Curiae **Lymphoma Foundation of America** is a national non-profit organization devoted to helping lymphoma patients and their families. Lymphoma refers to cancers of the lymph system and approximately 62,000 new cases are diagnosed each year. The Lymphoma Foundation provides counseling, support groups, referrals and public education, and it maintains a public web site. *See* <http://www.lymphomahelp.org/> Based on its history with thousands of patients, it is the Lymphoma Foundation's experience that, for some patients, marijuana is an efficacious and at times necessary treatment for nausea, vomiting, and lack of appetite – serious, sometimes life-threatening symptoms that afflict many lymphoma patients undergoing chemotherapy and radiation.

Amicus Curiae **HIV Medicine Association of the Infectious Diseases Society of America** ("HIVMA") is a national organization of more than 2600 physicians and other health professionals who practice HIV medicine. HIVMA is committed to ensuring that public policies related to HIV prevention, research and treatment are grounded in science and informed by social justice.

Amicus Curiae **American Medical Student Association** ("AMSA") is the oldest and largest independent association of physicians-in-training in the United States. Founded in 1950, AMSA is a student-governed, non-profit organization committed to representing the concerns of physicians-in-training. AMSA began under the auspices of the American Medical Association (AMA) to provide medical students a chance to participate in organized medicine. Starting in 1960, the association refocused its energies on the problems of the

medically underserved, inequities in our health-care system and related issues in medical education. With approximately 50.000 members, including medical and premedical students, residents and practicing physicians, AMSA is committed to improving medical training as well as advancing the profession of medicine.

Amicus Curiae **Barbara Roberts, Ph.D.**, served as a senior policy analyst and acting deputy director for demand reduction in the Office of National Drug Control Policy of the White House ("ONDCP") for ten years, until August 2003. During her tenure with the ONDCP, Dr. Roberts specifically recommended that the National Institute of Medicine of the National Academy of Sciences ("IOM") be commissioned to undertake a review of the scientific evidence regarding therapeutic applications of marijuana. Dr. Roberts supports the IOM Report and its recommendations. Additionally, Dr. Roberts has been a treating clinician for the National Football League in its Program for Substance Abuse since 1997. Dr. Roberts is currently a Clinical Associate Professor in the Department of Psychiatry at Georgetown University Medical Center, and she serves as President of the District of Columbia Psychological Association for the 2004-2005 term. Dr. Roberts is also an appointed member of the licensing board for the District of Columbia Board of Psychology, which is the agency responsible for overseeing the practice of psychology in Washington, D.C. Dr. Roberts believes in the importance of scientific research into the medical uses of marijuana.

Amicus Curiae **Irvin Henry Rosenfeld** was born in 1953 and diagnosed at age 10 with multiple congenital cartilaginous exostosis, a disease causing the continuous growth of bone tumors, and the generation of new tumors, on ends of most of the long bones of his body. He was told he would probably not survive into adulthood. In an attempt to

treat the painful symptoms of the disease, he was prescribed high doses of opioid analgesics, muscle relaxants, and anti-inflammatory medications, which he took on a daily basis, but which had minimal efficacy and produced debilitating side effects. In 1971, Mr. Rosenfeld began using smoked herbal cannabis with the approval and under the supervision of a team of physicians. Mr. Rosenfeld found the cannabis highly efficacious in alleviating pain, reducing swelling, relaxing muscles and veins that surround the bone tumors, and preventing hemorrhaging. In November 1982, the United States government, operating under the Compassionate Care IND Program, and at the request of Mr. Rosenfeld's physicians, began supplying Mr. Rosenfeld with herbal cannabis for medical use – *i.e.*, to treat his condition. Mr. Rosenfeld was the second patient accepted into the Compassionate Care IND Program and he is the longest-surviving participant. Presently, the federal government supplies Mr. Rosenfeld with a 150-day supply of medical cannabis, totaling 66 ounces per shipment. Mr. Rosenfeld smokes 12 marijuana cigarettes a day to control and alleviate the symptoms of his disease. During the more 33 years that Mr. Rosenfeld has used herbal cannabis as a medicine, he has experienced no adverse side-effects (including no "high"). Further, Mr. Rosenfeld has been able to discontinue his prescription medications and has worked successfully for the past 18 years as a stockbroker handling millions of dollars in accounts. Mr. Rosenfeld and his physicians believe that but for medical cannabis Mr. Rosenfeld might not be alive or, at the very least, would be bed-ridden.

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Supreme Court of the United States

JOHN ASHCROFT,
ATTORNEY GENERAL, *ET AL.*,

Petitioner,

v.

ANGEL McCLARY RAICH, *ET AL.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF THE NATIONAL ORGANIZATION FOR THE REFORM OF MARIJUANA LAWS (NORML), THE NORML FOUNDATION, THE NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS (NACDL), WASHINGTON ASSOCIATION OF CRIMINAL DEFENSE LAWYERS (WACDL), AND OREGON CRIMINAL DEFENSE LAWYERS ASSOCIATION (OCDLA) AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI*[1]

The National Organization for the Reform of Marijuana Laws (NORML) was organized in 1970, and participates in the public policy debate over marijuana policy for the tens of millions of adult Americans who use marijuana responsibly. NORML lobbies for the rights of responsible marijuana users and other taxpayers and voters who oppose current prohibition policies. NORML has more than 5,000 financial supporters in every state. It also has a grassroots political network of more than 18,000 volunteer activists, including 60 state and local affiliated organizations, who oppose the criminal prohibition of marijuana. The NORML Foundation raises and spends money for work and advocacy in the area of marijuana law reform.

NORML has long supported policies and legislation that would permit seriously ill patients to use cannabis as a medicine when recommended by their physician. NORML opposes the use of marijuana by children and adolescents, and it has published a set of guidelines for responsible marijuana smoking entitled "Principles of Responsible Cannabis Use."

NORML first asserted the medical use of cannabis in 1972 in an administrative petition asking the federal government to move cannabis from schedule I to schedule II of the Controlled Substances Act so doctors could prescribe it. After two years of administrative hearings, in 1988 a DEA Administrative Law Judge (a retired federal judge) found: "Marijuana has been accepted as capable of relieving distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this

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[1] Pursuant to S.Ct. Rule 37.6, counsel certifies that no counsel for a party authored any part of this brief. No person or entity other than *amici* made a monetary contribution to the preparation or submission of the brief.

Pursuant to S.Ct. Rule 29.6, NORML, the NORML Foundation, and NACDL are nonprofit corporations. They have no parent corporation, they are not publicly held, nor does a publicly held company own 10% or more of their stock. They are 501(c) (3 & 4) nonprofits.

substance in light of the evidence in this record."[2] The ALJ there recommended "that the Administrator transfer marijuana from Schedule I to Schedule II, to make it available as a legal medicine." The DEA Administrator rejected this conclusion, and the Court of Appeals for the District of Columbia Circuit affirmed.[3] The DEA, however, has its own Compassionate IND program where the federal government gives medical cannabis to a remaining handful of patients, as long as they are alive. In the past 25 years, NORML has litigated several times the issue of medical use of cannabis in federal courts and administratively before the DEA.[4] With reclassification blocked by the DEA, NORML has continued to advocate the medical use of cannabis and to support state and federal legislation and voter initiatives to that end.

The National Association of Criminal Defense Lawyers (NACDL) is the preeminent bar organization advancing the mission of the nation's criminal defense lawyers to ensure justice and due process for persons accused of crime. Founded in 1958, NACDL has more than 11,400 direct members and 80 state and local affiliate organizations with nearly 30,000 members committed to preserving the Bill of Rights. The American Bar Association recognizes NACDL as an affiliate organization on its House

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[2] *In The Matter of Marijuana Rescheduling Petition*, Docket No. 86-22 (Sept. 6, 1988).

[3] *Marijuana Scheduling Petition*, 54 Fed. Reg. 53767, 53784 (Dec. 29, 1988), *aff'd Alliance for Cannabis Therapeutics v. DEA*, 304 U.S. App. D.C. 400, 15 F.3d 1131 (1994).

[4] NORML has always been a party in the "marijuana rescheduling" cases seeking federal recognition of the medical use of cannabis. *See, e.g.*, the related cases of *Alliance for Cannabis Therapeutics v. DEA, supra; Alliance for Cannabis Therapeutics v. DEA*, 289 U.S. App. D.C. 214, 930 F.2d 936 (1994); *NORML v. DEA*, 182 U.S. App. D.C. 114, 559 F.2d 735 (1977); *NORML v. Ingersoll*, 162 U.S. App. D.C. 67, 497 F.2d 654 (1977).

There is another rescheduling case pending now, the petitioners being the Coalition for Rescheduling Cannabis, a consortium of eleven organizations, including NORML. The petition was filed with the DEA on October 9, 2002, but the DEA did not state that it formally accepted it until April 3, 2003. In July 2004, the DEA referred it to the Department of Health and Human Services under 21 U.S.C. § 811. (There are no docket numbers.)

of Delegates. NACDL promotes study and research in the field of criminal law. In furtherance of its objectives over the past decade, NACDL files approximately ten *amicus* briefs a year with this Court on criminal justice issues defending the Bill of Rights.

NORML and NACDL together filed an *amicus* brief in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001).

The Washington Association of Criminal Defense Lawyers and the Oregon Criminal Defense Lawyers Association are both state affiliates of NACDL. Both states have medical marijuana laws, and the criminal defense lawyers in those states defend the rights of their clients to use medical marijuana.

The parties have consented to the filing of this *amici* brief on behalf of the respondents, and the letters of consent are filed with this brief.

SUMMARY OF ARGUMENT

I. A. This case is about the confluence of the state and individual rights: A state's capacity to legislate its public health policy, by choosing its own means and ends to achieve what it believes best serves the good of its people, when there is no superior or even competing federal interest; and, the right of personal medical choices of the chronically and terminally ill, made in consultation with their doctors. This state-federal conflict implicates several individual liberties intertwined under our Constitution: The right of the "pursuit of happiness" and liberty by the chronically and terminally ill; the right of citizens "to be let alone" by government in personal decisions; and substantive due process when there is no comparable federal interest in prohibiting the conduct at issue.

B. Many sick people are not aided at all by conventional drug therapy for serious medical conditions. Cannabis, however, may provide them relief that conventional drug therapy cannot. The medical use of cannabis has been recognized for at least 5,000 years. Hundreds of articles, books, and reports deal with the efficacy of cannabis for

medicinal use and reputable drug companies, still in existence, such as Eli Lilly & Co. and Parke, Davis & Co., sold it. Ten states with 22% of the nation's population, nearly one-quarter, have legalized the medical use of cannabis.

II. A. No form of legislation is more fundamental than the right of the people of the American states to enact laws by initiative. This power is reserved to the people and the states under the Ninth and Tenth Amendments. In the ten states where the people have determined by their political and legislative processes that medical use of cannabis for the chronically or terminally ill is a right and a choice made between doctor and patient, medical cannabis is elevated to a privacy and due process right. The federal government has a duty to respect these states' decisions, and has no law enforcement or public safety interest in criminalizing the medical use of cannabis in those states.

B. Unless the federal government has sought to preempt the field, which it expressly has not done with drug laws under the Controlled Substances Act, 21 U.S.C. § 903, the Supremacy Clause does not prohibit states from enacting laws in the same area.

III. There is a constitutional right of privacy and substantive due process right in the medical use of cannabis when the decision is made under state law between a doctor and a chronically or terminally ill patient seeking to preserve a tolerable quality of life, under three separate but interrelated constitutional theories:

A. The decision to use medical cannabis can be the difference between a horrible existence or a minimal quality of life as death approaches. When sentient life becomes almost unbearable, anything that improves it takes on constitutional dimension. People have the right to define their own concept of existence. That right is the essence of the natural law upon which the Declaration of Independence, its "pursuit of happiness" and due process of law are founded. *Cruzan* holds that due process includes protection of the quality of life, and that applies here.

B. Implicit in the Bill of Rights is the "right to be let alone" by government. In *Winston v. Lee,* this Court

recognized that some parts of the "right to be let alone" are more important than the government's interest in doing what it wants. The personal medical decision to use medical cannabis to alleviate suffering is such a right.

C. The right to medical use of cannabis is also protected by substantive due process because both pain relief and the use of medical cannabis are recognized in our "history, legal traditions, and practices." The right to substantive due process must insure that chronically and terminally ill Americans should have the right to doctor-approved medical use of cannabis if it alleviates their debilitating suffering or improves their quality of life in their time left before their death.

IV. The claim that federal drug law enforcement is harmed by medical use is untenable. Whatever one's stance on the "war on drugs," the prosecution of drug offenses by the state and federal governments will go on unabated even if state chartered cannabis buyers' clubs are permitted to operate. The class of potential offenders that the federal government has selected are not drug abusers, but patients with doctor recommendations for treatment. The law enforcement and judicial machinery otherwise never would waste resources on such offenders. This issue involves no meaningful interest of the federal government, other than an opportunity to make a symbolic political statement in the "war on drugs." Casualties in the "war on drugs" should not be the chronically and terminally ill who are aided by medical use of cannabis.

ARGUMENT

I. Introduction

A. What this case is and what it is not

Amici submit that the government trivializes the legal and health issues in this case by framing the issue as "*purported* personal 'medicinal' use or the distribution of marijuana without charge for such use." Petition at I (emphasis added). This case is about the bona fide medicinal use of cannabis by the chronically ill and dying in California where other medication has failed to alleviate

their condition, pursuant to an initiated act adopted by the people of California, and, by extension, in the nine other states that have legislatively legalized medicinal use of cannabis.

The Respondent medicinal cannabis-using patients assert the fundamental right to enhance the quality of whatever is left of their lives, when other more conventional treatment and medication have failed to relieve suffering. This case also concerns the fundamental right to exercise legislative power as reserved by the Ninth and Tenth Amendments, to the people of ten states, although only California is presently before the Court. Finally, this case presents an exercise of law enforcement authority by the federal government in a narrow area where it lacks any constitutional power to act under the Ninth and Tenth Amendment because this is a power reserved to the people and the States. On this record, there is utterly no federal interest in this case: the cannabis is locally grown, given away to those with a prescription, it is limited to those with a proven bona fide medical need, and there is no economic issue whatsoever in this case. Moreover, there is no indication in the Controlled Substances Act (CSA) that it is designed or intended to reach such activity because the CSA expressly permits the states to legislate as they please under 21 U.S.C. § 903.

Popularly enacted legislation permitting compassionate medical use of cannabis is an assertion of a fundamental right by the people and the states where the federal government has failed to act. Those state laws here recognize a right for patients who have lost any real quality of life from chronic or terminal illness to be free from unnecessary pain and suffering. Enabling patients whose medical conditions deny them a quality of life to use medical cannabis with their doctor's oversight is a matter fully reserved to the people and the states under the Ninth and Tenth Amendments that the federal government must respect. The federal government has no power to legislate in this area under either the commerce clause or "necessary and proper" clause of Art. I, § 8 of the Constitution. "The government . . . can claim no powers which are not granted to it by the Constitution, and the powers actually

granted, must be such as are expressly given, or given by necessary implication." *Martin v. Hunter's Lessee,* 14 U.S. (1 Wheat.) 304, 326 (1818).

This case involves numerous fundamental interests at risk in the attempt by the federal government to prohibit what California and nine other states have allowed. This exercise of rights by the people and the states to legislate in matters of personal human dignity is protected from federal abrogation or interference under our fundamental concept of ordered liberty and federalism. Where there is a personal medical choice made in consultation with a doctor, where there is no compelling conflicting federal interest, the people and states are constitutionally entitled to legislate what means they believe better serve their own defined goals. This conflict implicates multiple intertwined individual liberties under our Constitution: The right of the "pursuit of happiness" and liberty by the chronically and terminally ill; the right of people "to be let alone" by their government in these personal decisions; and substantive due process, particularly when there is no serious or even marginally compelling federal interest in prohibiting the conduct at issue.

B. The history, efficacy, and public acceptance of the medical use of cannabis

Cannabis has been recognized as having legitimate medical use for 5,000 years,[5] and possibly 10,000 years,[6]

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[5] LESTER GRINSPOON, M.D. & JAMES B. BAKALAR, MARIHUANA: THE FORBIDDEN MEDICINE 3-5 (Rev.ed. 1997) ("The first evidence of the medicinal use of cannabis is an herbal published during the reign of Chinese Emperor Chen Nung five thousand years ago. [¶] It was listed in the United States Dispensatory in 1854. . . . Commercial cannabis preparation could be bought in drug stores. . . . [¶] Meanwhile, reports on cannabis accumulated in the medical literature."). *See Regina v. Parker, infra,* ¶ 123:

> Like many other herbs, marihuana has been used in Asian and Middle Eastern countries for at least 2600 years for medicinal purposes. It first appeared in Western medicine in 60 A.D. in the Herbal (i.e. pharmacopoeia) of Dioscorides and was listed in subsequent herbals or pharmacopoeia since that

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including a wealth of modern articles on the utility of the medicinal use of cannabis, and the history of cannabis use in the United States beginning before our colonization.[7] The most recent books citing published findings are: LESTER GRINSPOON, M.D. & JAMES B. BAKALAR, MARIHUANA: THE FORBIDDEN MEDICINE (Rev.ed. 1997) and NATIONAL ACADEMY OF SCIENCES'S INSTITUTE OF MEDICINE, MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE (1999).[8] Indeed, medicinal cannabis was recognized in the medical literature of the United States since the mid-1800's.[9] Medical cannabis

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time. Marihuana was widely used for a variety of ailments, including muscle spasms, in the nineteenth century. In the 1930's, the advent of synthetic drugs led to the abandonment of many ancient herbal remedies including marihuana, although an extract of cannabis and a tincture of cannabis remained in the British Pharmaceutical Codex of 1949.

[6] Declaration of Lester Grinspoon, M.D., Appendix B.

[7] GRINSPOON & BAKALAR, *supra*, Ch. 1.

Some of our founding fathers were hemp growers. Bergoffen & Clark, *Hemp as an Alternative to Wood Fiber in Oregon*, 11 J.ENVTL.L. & LITIG. 119, 120-21 (1996):

> In North America, hemp was widely used before European settlement, contrary to popular views. . . . John De Verrazano discovered it growing wild in Virginia in 1524. It is also well established that marijuana has been used for both religious and recreational purposes for thousands of years.
>
> . . . In Virginia in the 1760s, a bounty of "four shillings for every gross hundred of hemp" was to be paid to farmers. Most famous of these Virginia hemp farmers were George Washington and Thomas Jefferson; Jefferson considered hemp so important that he even arranged to smuggle Chinese hemp seeds back to the United States because of their superior qualities. Another forefather, Benjamin Franklin, founded one of America's first paper mills which used hemp as its fiber source.

[8] The latter is online at http://bob.nap.edu/books/0309071550/html/, last visited Oct. 8, 2004.

[9] Grinspoon wrote, *supra*, note 5, that medical cannabis was in the UNITED STATES DISPENSATORY in 1854. Medicinal cannabis was distributed or recommended by all sorts of respected and well-known drug companies at the end of the Nineteenth Century and beginning of the Twentieth, companies still around today: *See, e.g.*,

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fell into disuse by the confluence of Prohibition and the development of patent medicines. Grinspoon Aff. ¶s 12-13, Appendix B. Dr. Grinspoon is the world's foremost authority on medicinal marijuana.

Even the DEA's ALJ recognized the case for the medical use of cannabis presented by NORML was *never refuted* by the agency. The DEA would not hear of it, however, and refused to adopt the ALJ's recommendation despite the uncontradicted evidence. (*See* notes 2-4, *supra*.) No wonder, then, that the states acted to legalize medicinal use of cannabis. The federal government must respect the choice of these states.

Many influential American and other medical organizations and health care providers today recognize that there is a bona fide need for the medical use of cannabis when a doctor and patient decide it is necessary. *See* Appendix A. This should be a fundamental personal choice in which the federal government should have no say.

Parke, Davis & Co.: INDEX OF DISEASES AND REMEDIES 192-93 (1890); PHYSICIAN'S MANUAL OF THERAPEUTICS 274-76 (1901); COMPLETE CATALOG OF THE PRODUCTS OF THE LABORATORIES OF PARKE, DAVIS & CO. (rev. Dec. 1, 1915, Jan. 2, 1927, Mar. 1, 1937).

Eli Lilly & Co.: *Lilly's Bulletin* (Feb. 1892); PHARMACEUTICAL CHEMISTS 32 (5th rev. 1898); HANDBOOK OF PHARMACY AND THERAPEUTICS 53, 71, 75 (6th rev. 1919).

Medical use of cannabis was also listed in the basic medical literature at the beginning of the Twentieth Century: *see, e.g.*, MORSE STEWART, M.D., POCKET THERAPEUTICS AND DOSE-BOOK 74 (4th ed. 1910); WALTER A. BASTEDO, M.D., MATERIA MEDICA: PHARMACOLOGY: THE THERAPEUTICS OF PRESCRIPTION WRITING 368 (1914); HOBART AMORY HARE, A TEXT-BOOK OF PRACTICAL THERAPEUTICS 166-68 (16th ed. 1916); THE PHARMACOPŒIA OF THE UNITED STATES OF AMERICA 95 (10th ed. 1926); *Id.* at 155 (11th ed. 1936); SAMUEL O.L. POTTER, M.D., THERAPEUTICS: MATERIA MEDICA AND PHARMACY 205-07 (14th ed. 1926); DAVID M.R. CULBRETH, M.D., A MANUAL OF MATERIAL MEDICA AND PHARMACOLOGY 165-70 (7th ed. 1927); A.S. BLUMGARTEN, M.D., TEXTBOOK OF MATERIA MEDICA 338-39 (5th ed. 1931); E. FULLERTON COOK, P.D., PH.M. & CHARLES H. LAWALL, PH.M, PHARM.D., REMINGTON'S PRACTICE OF PHARMACY 401, 413, 421, 456, 515 (8th ed. 1936); THE DISPENSARY OF THE UNITED STATES OF AMERICA 275-78 (22d ed. 1937). *See* also the authorities cited in note 5, *supra*.

II. Federalism and the Commerce Clause require that this Court recognize that medical use of cannabis is a matter reserved to the people and the States under the Ninth and Tenth Amendments

This case presents the recognition of important legal doctrines at the heart of our form of constitutional government: individual liberty and the powers reserved to the people and the States. As a matter of individual liberty, it should be beyond the power of the federal government to regulate the medicinal use of cannabis when the voters or legislatures of states decide it should be legalized for medical use. (Point III, *infra*) Ten states with 22% of the population have approved of the medical use of cannabis since 1996: Nine by initiative and one by the state legislature. The public and medical organizations strongly support medical cannabis use for those who would be aided by it. (Appendix A)

It is only natural, then, that the proponents of the medical use of cannabis go directly to the people when a state legislature or the federal government fails to act. It is, no doubt, a natural political right. And, as James Madison would say: It is none of the federal government's business.

A. Federalization of a purely local concern in violation of the Tenth Amendment

This case involves federalization of a quintessentially local activity: the production and consumption of purely locally grown and distributed cannabis solely for medicinal reasons by seriously ill Californians whose condition is not alleviated by other drugs.[10] It is undisputed on this record

[10] Oregon's Department of Human Services reports, as of July 1, 2004, 10,196 registered patients, 5,384 registered caregivers, and 1,413 registered physicians, with the following conditions described for the patients:

Conditions*

*A patient may have more than one diagnosed qualifying medical condition.

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that the cannabis involved here does not "substantially affect interstate commerce," *United States v. Lopez,* 514 U.S. 549, 559 (1995), or that any purported link to interstate commerce is attenuated at best. *United States v. Morrison,* 529 U.S. 598, 610-12 & n.4 (2000). It is a case involving respect for "the constitutional role of States as sovereign entities"; *Alden v. Maine,* 527 U.S. 706, 713 (1999); to prosecute their own crimes under the Tenth Amendment[11] because the Controlled Substances Act does not preempt state law. 21 U.S.C. § 903.

Agitation related to Alzheimer's disease	<50
Cachexia	438
Cancer	335
Glaucoma	198
HIV+/AIDS	221
Nausea	2134
Pain	8711
Seizures, including but not limited to epilepsy	316
Persistent muscle spasms, including but not limited to those caused by multiple sclerosis	2691

www.ohd.hr.state.or.us/publichealth/mm/ (last visited Oct. 8, 2004).

[11] *Printz v. United States,* 521 U.S. 898, 918 (1997):

> It is incontestible that the Constitution established a system of "dual sovereignty." *Gregory v. Ashcroft,* 501 U.S. 452, 457 (1991); *Tafflin v. Levitt,* 493 U.S. 455, 458 (1990). Although the States surrendered many of their powers to the new Federal Government, they retained "a residuary and inviolable sovereignty," THE FEDERALIST No. 39, at 245 (J. Madison) . . . Residual state sovereignty was also implicit, of course, in the Constitution's conferral upon Congress of not all governmental powers, but only discrete, enumerated ones, Art. I, § 8, which implication was rendered express by the Tenth Amendment's assertion that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

JAMES MADISON, THE FEDERALIST No. 39, *supra*:

> In the latter, the local or municipal authorities form distinct and independent portions of the supremacy, no more subject within their respective spheres of authority, than the general

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Amici submits that, in attempting to prosecute the crime of possession of cannabis for legitimate medical purposes, recognized by a sovereign state of the United States, the federal government exceeded its power under the Commerce Clause, Art. I, § 8, cl. 3, of the U.S. Constitution. To paraphase this case using *Lopez*:

> [t]he possession of a [medically prescribed cannabis] [o]n [ ] local [farm land or for local medical use] is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce. Respondent was a local [medical user for himself] at a local [dispensary]; there is no indication that he had recently moved in interstate commerce, and there is no requirement that his possession of the [medically prescribed cannabis] ha[s] any concrete tie to interstate commerce.

Lopez, 514 U.S. at 567, quoted *infra* (bracketed material added).

This is an issue of first impression for this Court, and it was apparently reserved in *United States v. Oakland Cannabis Buyers' Coop.,* 532 U.S. 483, 495 n.7 (2001).[12]

Applying *Lopez* and its progeny, particularly *United States v. Morrison,* 529 U.S. 598, 610-12 (2000), the record here demonstrates that the use of medicinal cannabis here is not an economic or commercial enterprise, so *Wickard v. Filburn,* 317 U.S. 111 (1942), does not come into play under *United States v. Morrison,* 529 U.S. at 611 n.4. Second, the findings of Congress in 21 U.S.C. § 801 as to interstate character of drug trafficking has no application

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> authority is subject to them within its own sphere. In this relation then, the proposed government cannot be deemed a NATIONAL one; since its jurisdiction extends to certain enumerated powers only, and leaves to the several states a residuary and inviolable sovereignty over all other objects.

[12] *Oakland Cannabis,* 532 U.S. at 495 n.7: "Nor are we passing today on a constitutional question, such as whether the Controlled Substances Act exceeds Congress' power under the Commerce Clause."

to the facts on this record; just because Congress says it does not make it so, and this Court must look behind those findings. *Morrison,* 529 U.S. at 614; *Lopez,* 514 U.S. at 566-67. Finally, the link between the sought to be regulated activity and its effect on interstate commerce is "attenuated" at best. *Morrison, supra,* at 612.

B. The power of the people to initiate legislation is reserved to the people and the States by the Ninth and Tenth Amendments

The power of initiative and referendum appears in about half of the state constitutions,[13] as it does in California. Cal. Const., Art. 4, § 1. This quintessential reservation of political and legislative power is expressly reserved to the people and the States under the Ninth and Tenth Amendments.[14] In addition, the initiative power is clothed with full First Amendment protection as "core political speech" and a method of petitioning government for redress of grievances.[15]

As Justice STEVENS stated concurring on *Oakland Cannabis Buyers' Coop., supra,* 532 U.S. at 501, this Court, as a federal institution, must

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[13] *Lucas v. Forty-Fourth General Assembly,* 377 U.S. 713, 734 (1964).

[14] *Cammarano v. United States,* 358 U.S. 498, 506 (1959) (state constitutions "explicitly recognize that in providing for initiatives they are vesting legislative power in the people.").

[15] *See Meyer v. Grant,* 486 U.S. 414, 421-22 (1988):

> The circulation of an initiative petition of necessity involves both the expression of a desire for political change and a discussion of the merits of the proposed change. [A] petition circulator . . . will at least have to persuade them that the matter is one deserving of the public scrutiny and debate that would attend its consideration by the whole electorate. This will in almost every case involve an explanation of the nature of the proposal and why its advocates support it. Thus, the circulation of a petition involves the type of interactive communication concerning political change that is appropriately described as "core political speech."

> show[] respect for the sovereign States that comprise our Federal Union. That respect imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country. (internal quotation marks omitted)

C. Federal deference to state law on the medical use of cannabis, and the inapplicability of the Supremacy Clause

Once the voters of a state have adopted an initiative or a state legislature has enacted a statute protecting the medical use of cannabis, the people of that state have compellingly expressed their public policy, even if that public policy differs from that of the federal government. Federalism mandates that state public policy is entitled to presumptive deference. State legislation expresses its public policy; *Schall v. Martin,* 467 U.S. 253, 281 (1984); especially legislation adopted directly by the people.[16]

The Supremacy Clause, U.S. Const., Art. IV, cl. 2, provides the federal government no support in its attempt to nullify this state law because Congress has not even remotely attempted to preempt every part of the field of criminalizing drug crimes; indeed, 21 U.S.C. § 903 expressly allows the States to legislate as they choose, and every state has laws against the illegal use, manufacture, and distribution of controlled substances. And, the federal government could not preempt drug regulation even if it wished, because the federal government possesses no

[16] Also, "state legislatures are *not* subject to federal direction. *New York v. United States,* 505 U.S. 144 (1992)." *Printz v. United States,* 521 U.S. 898, 912 (1997) (emphasis in original).

A fortiori, if a legislature is not subject to federal direction, neither are the people acting through the initiative process.

general federal police power, a power singularly reserved to the states. *Lopez v. United States,* 514 U.S. at 560 n.3.

Federal and state drug laws have co-existed for more than 60 years, and state laws recognizing medical use of cannabis manifestly do not "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Pacific Gas & Electric Co. v. State Energy Resources Conservation and Development Comm.,* 461 U.S. 190, 203-04 (1983) (quoting *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941)). The federal government can fully prosecute the more significant drug crimes as it should and just stay out of the business of the states.[17]

Congress cannot remain in denial of factual reality and cannot declare night to be day and simply expect this Court to rubberstamp that conclusion any more. *Lopez,* 514 U.S. at 566-67. In the realm of state and federal drug offenses, *Kelly v. Washington ex rel. Foss Co.,* 302 U.S. 1, 9-10 (1937), answers this question for us:

> Under our constitutional system, there necessarily remains to the States, until Congress acts, a wide range for the permissible exercise of power appropriate to their territorial jurisdiction although interstate commerce may be affected. . . . States are thus enabled to deal with local exigencies and to exert in the absence of conflict with federal legislation an essential protective power. And when Congress does exercise its paramount authority, it is obvious that Congress may determine how far its regulation shall go. There is no constitutional rule which compels Congress to occupy the whole field. Congress may circumscribe its regulation and occupy only a limited field. When it does so, state regulation outside that limited field and otherwise admissible is not

[17] The federal government still dabbles in medicinal cannabis use, actually providing it to a declining (as they die off) number of patients. If the states want to explore this further, the federal government should just stay out of it.

> forbidden or displaced. The principle is thoroughly established that the exercise by the State of its police power, which would be valid if not superseded by federal action, is superseded only where the repugnance or conflict is so "direct and positive" that the two acts cannot "be reconciled or consistently stand together." (citations omitted)

Thus, unless Congress dictates that the states may not regulate drug crimes, something it will never do, the federal government cannot claim preemption. Indeed, the CSA says otherwise in 21 U.S.C. § 903.

III. The right of liberty, privacy, and substantive due process in medical use of cannabis

There is a constitutional right of privacy and a substantive due process right in the medical use of cannabis when that decision is made under state law between a doctor and a chronically or terminally ill patient seeking to preserve a tolerable quality of life. This right is more significant when patients seek to preserve some semblance of human dignity and freedom from the ravages of disease in their final days. This principle is founded on three interrelated constitutional theories:

A. Rights to the dignity of life, individual liberty and autonomy, and the "pursuit of happiness"

For some patients, the decision to use medical cannabis can be the difference between a horrible existence or a minimal quality of life as death approaches. When a state has permitted the use of medical cannabis for these people, after conventional medication has failed or forced them to suffer intolerable side effects, their very ability to define their life is at stake. When the quality of life becomes almost unbearable, anything that improves the quality of life has constitutional dimension. "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define

the attributes of personhood were they formed under compulsion of the State." *Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833, 850-51 (1992).

Indeed, "defin[ing] one's own concept of existence" is the essence of the natural law expressed in ¶ 2 of the Declaration of Independence: "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty, and the pursuit of Happiness." As the Court stated in *Board of Regents v. Roth,* 408 U.S. 564, 572 (1972), the Court has not attempted to define with exactness the liberty guaranteed by due process, because, "[i]n a Constitution for a free people, there can be no doubt that the meaning of 'liberty' must be broad indeed." In Respondent Angel Raich's situation, liberty is having any quality of life at all. Cannot the federal government do anything to insure the quality of life rather than interfere with it?

> Our Constitution is born of the proposition that all legitimate governments must secure the equal right of every person to "Life, Liberty, and the pursuit of Happiness." In the ordinary case we quite naturally assume that these three ends are compatible, mutually enhancing, and perhaps even coincident.
>
> . . . Together, these considerations suggest that Nancy Cruzan's liberty to be free from medical treatment must be understood in light of the facts and circumstances particular to her.

Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261, 331 (1990) (STEVENS, J., dissenting) (footnote omitted).

A state has an "unqualified interest in the preservation of human life." *Cruzan,* 497 U.S. at 282. Because of that interest, states sometimes seek the preservation of life notwithstanding the utter lack of quality of that life. Thus, Nancy Cruzan's family had to fight the State of Missouri which wanted to keep her alive by state mandated medical intervention. Like the state in *Cruzan,* the federal government tells us that patients who want to

preserve their own life, who are struggling to stay alive despite painful or debilitating side effects of modern medicine, have no right to preserve any semblance of dignity of their waning life by medical procedures approved by the voters of their state. The sovereign State of California, a state of over 35 million people, through its voters, have determined that the interest in the quality of life for the gravely ill by giving them relief from their condition, when other medicines have failed,[18] is more important than prosecution of those people for possession or cultivation or delivery of cannabis for medicinal purposes.

Is it not ironic that a prison inmate can be judicially forced to be medicated to have a quality of life on death row for the temporary preservation of his life, just so the state can later be able to execute him?[19] Yet here, the government denies a comparable right to the chronically or terminally ill patient who could benefit from the medical use of cannabis. This judicial distinction, to heal prisoners to enable the states to end their life, but to harm terminal patients holding on to life, is irrational and contrary to any concept of ordered liberty in a free nation.

If a state has such an "unqualified interest in the preservation of life," it must of necessity also have an interest in the quality of the life it preserves as the end of life approaches. In some situations, particularly the AIDS wasting syndrome, the medical use of cannabis usually provides the *only means to sustain life*. If so, then there

[18] *See, e.g., Regina v. Parker, infra,* where the Ontario Court of Appeals, in holding that medicinal use of cannabis was a right in Canada, noted that synthetic THC (Marinol®) failed Parker, but cannabis alleviated his suffering.

[19] A state may force inmates to take anti-psychotic medication to restore sanity when they are so disturbed that they have no quality of life and are a danger to themselves or others; *Washington v. Harper,* 494 U.S. 210 (1990); even if this medical intervention is forced on them, would make the inmates competent, and thus enable the state to execute them. *Singleton v. Norris,* 338 Ark. 135, 992 S.W.2d 768 (1999), *cert. den.* 528 U.S. 1084 (2000); *Singleton v. Norris,* 319 F.3d 1018 (8th Cir. 2003) (*en banc*), *cert. den.* 124 S. Ct. 74 (2003).

should be a constitutional right to use it, and, if there is no constitutional right, then the states should be freely able to legislate it.

B. The right to privacy in "the right to be let alone" by government

There is a basic right to privacy in this nation, "the right to be let alone," and it runs throughout the law of individual liberty. Whatever its source, be it in the common law,[20] the law of torts,[21] the Ninth Amendment, one of those "penumbra" rights within the Bill of Rights as a whole,[22] or whether it is a liberty interest under the due

[20] *See Union Pac. Ry. Co. v. Botsford,* 141 U.S. 250, 251 (1891), where a railroad sought a physical examination of an injured passenger. This Court affirmed the lower court's refusal to permit the examination of her body so the railroad could separately evaluate the seriousness of her injury:

> No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law. As well said by Judge Cooley: "The right to one's person may be said to be a right of complete immunity; to be let alone." Cooley, Torts, 29.

See Poe v. Ullman, 367 U.S. 497, 521 & n.12 (1961) (DOUGLAS, J., dissenting) ("The notion of privacy is not drawn from the blue. [n12: The right 'to be let alone' had many common-law overtones.] It emanates from the totality of the constitutional scheme under which we live.") & 543 (HARLAN, J., dissenting) (in addition, it protects against "arbitrary impositions and purposeless restraints" by government (quoting *Hurtado v. California,* 110 U.S. 516, 632 (1884)).

[21] *See generally* Warren & Brandeis, *The Right to Privacy,* 4 HARV. L. REV. 193 (1890); Prosser, *Privacy,* 48 CALIF. L. REV. 391 (1960); Griswold, *The Right to be Let Alone,* 55 NW. U. L. REV. 216 (1960).

[22] *Griswold v. Connecticut,* 381 U.S. 479, 484 (1965) (there is a penumbra of privacy rights, "zones of privacy," in the First, Third, Fourth, and Ninth Amendments); *Lawrence v. Texas,* 123 S. Ct. 2472 (2003) (states have no interest in prosecuting private consensual sex acts).

process clauses of the Fifth and Fourteenth Amendments,[23] government must recognize that certain rights reserved to the people and states are beyond its reach.

The phrase was truly memorialized in Justice Brandeis's famous dissent 76 years ago in *Olmstead v. United States,* 277 U.S. 438, 478 (1928):

> The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the Government, the right to be let alone – the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the Government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment.[24]

While the "right to be let alone" originally emerged into this Court's cases in a dissent, the existence of a constitutional right "to be let alone" is now well accepted. The Court has repeatedly cited *Olmstead* and considered "the right to be let alone" as a part, not only of the Fourth Amendment,[25]

[23] *Id.*, 381 U.S. at 493 (GOLDBERG, J., concurring) (due process and Ninth Amendment), 500 (HARLAN, J., concurring) (basic to concept of "ordered liberty" for due process) & 507 (WHITE, J., concurring) (due process violated because government cannot pass such a law); *Cruzan,* 497 U.S. at 279 n.7 (liberty interest under the Fourteenth Amendment in refusing medical treatment with a "right to die").

[24] Justice BRANDEIS also said, *id.* at 479: "The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding."

[25] *California Bankers Assn. v. Shultz,* 416 U.S. 21, 65 (1974); *Winston v. Lee,* 470 U.S. 753, 758-59 (1985). *See Katz v. United States,* 389 U.S. 347, 350-51 & n.6 (1967).

but also the First,[26] Fifth,[27] and Fourteenth[28] Amendments, not to mention the Ninth Amendment.[29]

The "right to be let alone" has been found to outweigh even one of the weightiest of governmental interests: The interest in procuring evidence to prosecute a violent crime. In *Winston v. Lee,* 470 U.S. 753, 765-66 (1985), the Court denied the government the ability to obtain evidence by forced major surgery on the body of the accused to remove a bullet, even where the search would certainly produce evidence of a violent crime:

> The Fourth Amendment protects "expectations of privacy," see *Katz v. United States,* 389 U.S. 347 (1967) – the individual's legitimate expectations that in certain places and at certain times he has "the right to be let alone – the most comprehensive of rights and the right most valued by civilized men." *Olmstead v. United States,* 277 U.S. 438, 478 (1928) (BRANDEIS, J., dissenting). Putting to one side the procedural protections of the warrant requirement, the Fourth Amendment generally protects the "security" of "persons, houses, papers, and effects" against official intrusions up to the point where the community's need for evidence surmounts a specified standard, ordinarily "probable cause." Beyond this point, it is ordinarily justifiable for the community to demand that the individual give up some part of his interest in privacy and security to advance the community's vital interests in law enforcement; such a search is generally "reasonable" in the Amendment's terms.

[26] *Stanley v. Georgia,* 394 U.S. 557, 564 (1969); *Rowan v. U.S. Post Office Dept.,* 397 U.S. 728, 736 (1970).

[27] *Tehan v. United States ex rel. Shott,* 382 U.S. 406, 416 (1966). *See United States v. Morton Salt Co.,* 338 U.S. 632, 651-52 (1950).

[28] *Eisenstadt v. Baird,* 405 U.S. 438, 453-54 n.10 (1972).

[29] *See Griswold v. Connecticut, supra.*

But, the Court held that this compelled surgical intrusion for evidence implicated expectations of privacy and personal security to such a degree that the intrusion was constitutionally unreasonable under the Fourth Amendment even though it certainly would produce evidence of a violent crime. *Id.* at 758-59. The government's normally compelling need to obtain vital evidence to enforce the criminal law and prosecute a violent criminal constitutionally had to give way to the personal dignity of the individual because the search was "unreasonable" under the Fourth Amendment.

That rationale applies with equal force here: No matter what the governmental interest in prosecuting drug crimes, the personal and fundamental interest in preserving the dignity of life should weigh more heavily, particularly when a sovereign state, the largest in the nation, no less, with nearly 35 million people, has declared its public policy through a vote of the people, that its citizens are entitled to the benefit of the medical use of cannabis in small quantities, locally produced.

C. Substantive due process: "history, legal traditions, and practices"

Analogous to the above two standards and using similar language, but still clearly a standard of its own, is the right to substantive due process under the Fifth and Fourteenth Amendments. If the right to substantive due process means anything, it should mean that chronically and terminally ill Americans should have the right to medical use of cannabis if it alleviates suffering from a serious medical condition and thereby adds some quality of life in the time left before death. This Court has already recognized a substantive due process right to be free from pain and suffering in *Cruzan,* involving a woman who was in a persistent vegetative state whose family wanted to have a feeding tube withdrawn so she could die and be allowed to be free of her misery. *A fortiori,* it naturally flows from that case that there also is a parallel right patients in chronic pain or the terminally ill to alleviate

pain and suffering *when they want to live.* Nancy Cruzan had a right to stop being force fed and to die to alleviate her pain and suffering that was caused merely by her being kept alive in that condition. For patients who, with their doctors' approval, want to go on living but without their pain and suffering, they also have an "unqualified interest in the preservation of human life." "Life" must also mean "quality of life," however the states chose to permit it.

After *Cruzan,* this Court held in *Washington v. Glucksberg,* 521 U.S. 702 (1997), that there was no due process right to assisted suicide. The Court stated its approach to due process issues; *id.* at 710:

> We begin, as we do in all due-process cases, by examining our Nation's history, legal traditions, and practices. *See, e.g., Casey,* 505 U.S. at 849-850; *Cruzan,* 497 U.S. at 269-279; *Moore v. East Cleveland,* 431 U.S. 494, 503 (1977) (plurality opinion) (noting importance of 'careful "respect for the teachings of history" ')."

This substantive due process analysis derives from Justice HARLAN'S dissent in *Poe v. Ullman,* 367 U.S. 497, 542-43 (1961), elucidating the true meaning of "the full scope of liberty" under due process:

> It is this outlook which has led the Court continuingly to perceive distinctions in the imperative character of Constitutional provisions, since that character must be discerned from a particular provision's larger context. And inasmuch as this context is one not of words, but of history and purposes, the full scope of the liberty guaranteed by the Due Process Clause cannot be found in or limited by the precise terms of the specific guarantees elsewhere provided in the Constitution. This "liberty" is not a series of isolated points pricked out in terms of the taking of property; the freedom of speech, press, and religion; the right to keep and bear arms; the freedom from unreasonable searches and seizures; and so on. It is a rational continuum which,

> broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, . . . and which also recognizes, what a reasonable and sensitive judgment must, that certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgment. . . . (citations omitted)

Justice HARLAN'S opinion in *Poe* is recognized as the source of modern individual judicial review of substantive due process claims.[30]

Finally, in *Lawrence v. Texas,* 539 U.S. 558 (2003), this Court held that private consensual sex acts between adults could not be legislatively prohibited as a matter of due process. It was, simply put, no interest of state government. Where is the interest of the federal government in prohibiting medicinal marijuana when states authorize it? The personal decision to use medicinal cannabis to relieve pain and suffering, *when authorized by a state*, in consultation with a doctor, should be no less than the right to personal sexual autonomy when not authorized by a state, simply because due process demands it of the federal government.

[30] *Washington v. Glucksberg, supra,* at 766 n.4 (SOUTER, J., dissenting):

> The status of the Harlan dissent in *Poe v. Ullman,* . . . , is shown by the Court's adoption of its result in *Griswold v. Connecticut,* . . . , and by the Court's acknowledgment of its status and adoption of its reasoning in *Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833, 848-849 (1992). See also *Youngberg v. Romeo,* 457 U.S. 307, 320 (1982) (citing Justice HARLAN's *Poe* dissent as authority for the requirement that this Court balance "the liberty of the individual" and "the demands of an organized society"); *Roberts v. United States Jaycees,* 468 U.S. 609, 619 (1984); *Moore v. East Cleveland,* 431 U.S. 494, 500-506, and n.12 (1977) (plurality opinion) (opinion for four Justices treating Justice HARLAN's *Poe* dissent as a central explication of the methodology of judicial review under the Due Process Clause).

Our "history, legal traditions, and practices" unequivocally tell us that the individual is more important than the government and that government interference with a person's autonomy must be based on extremely important societal interests. In some cases, an individual's right to personal autonomy can outweigh even the undeniable powerful governmental interest in prosecuting violent crime, as in *Winston v. Lee.* Similarly, the right to personal autonomy in a private sexual act outweighs the government's power to criminalize, as in *Lawrence v. Texas.* We must never forget that our government exists to serve its citizens; the citizens do not exist to serve the government.[31] Moreover, medical use of cannabis is a part of our nation's history and the history of civilization for the last 5,000 or even 10,000 years. State authorized medical use of cannabis for patients with a dire need thus clearly qualifies for recognition under substantive due process "by examining our Nation's history, legal traditions, and practices."

D. The experience of Canada, Holland, and England

Canada's Charter of Rights was adopted only two decades ago, and it closely parallels our Bill of Rights; so much, indeed, that the Canadian courts apply American case law as an aid in interpreting their Charter.[32] Similarly, because of our geographic proximity and open border, political alliances, and similar adversary system with the same common law origin, this Court has looked to

[31] *See* the Declaration of Independence ¶s 3 & 28. *See also McCulloch v. Maryland,* 17 U.S. (4 Wheat.) 316, 405 (1819) ("The government . . . is emphatically, and truly, a government of the people. In form and in substance it emanates from them. Its powers are granted by them, and are to be exercised directly on them, and for their benefit.").

[32] *Regina v. Carter,* 2 C.R.R. 280, 144 D.L.R.(3d) 301, 304-05 (Ont. Ct. App. 1982) (American decisions may be persuasive). For example, running obvious queries ("U.S.," "F.3d," "Fourth Amendment") through their case data base on Lexis® will produce over 1,000 hits.

Canadian law and experience as an aid in interpreting our Bill of Rights.[33]

Section 7 of the Canadian Charter of Rights and Freedoms is the Canadian version of our Due Process Clause, and it provides that "[e]veryone has the right to life, liberty and security of the person and the right not to be deprived of those rights except in accordance with the principles of fundamental justice." The Ontario Court of Appeals found a fundamental right in the medical use of cannabis for the chronically ill, just as asserted here. The Canadian government has implementing medical use for distribution through its national health care system.[34] Thus, there is a right to the needful medical use of cannabis, notwithstanding that possession and delivery of cannabis otherwise remains a crime in Canada. *Regina v. Parker,* 49 O.R.(3d) 481, 75 C.R.R.(2d) 233, 188 D.L.R.(4th) 385, 2000 C.R.R. Lexis 96 (Ont. Ct. App. 2000) (right to use cannabis to control epilepsy; Marinol® was not helpful to Parker but cannabis was; medical necessity defense sustained as a fundamental right); *Regina v. Clay,* 49 O.R.(3d) 577, 75 C.R.R.(2d) 210, 188 D.L.R.(4th) 468, 2000 C.R.R. Lexis 97 (Ont. Ct. App. 2000) (no fundamental right to recreational possession of marijuana notwithstanding *Parker*'s recognition of a medical necessity right; both decided same day), *aff'd* [2003] 35 C.R. 735, 2003 S.C.C. 75, 2003 S.C.R. Lexis 675.

Parker was thus held to have a complete defense to criminal prosecution for his possession and cultivation of cannabis for his personal medical use. The Canadian

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[33] *See, e.g., Nixon v. Shrink Missouri Gov't PAC,* 528 U.S. 377, 403 (2000) (BREYER and GINSBURG, JJ, concurring); *Washington v. Glucksberg, supra,* at 713 (noting that Canadian courts had recently rejected a right to assisted suicide); *McIntyre v. Ohio Election Comm.,* 514 U.S. 334, 381 (1995) (SCALIA, J., dissenting).

[34] Harris, "Rock feels road to the PMO begins as a good health minister," *The Ottawa Citizen* A13, ¶ 14 (Jan. 28, 2001) (describing how the new health minister "has managed to get a formal medical-marijuana policy in place in Canada, including the identification of a supplier for the otherwise illegal drug.").

court's analysis in *Parker* closely parallels this Court's own due process analysis:

> [¶ 96] . . . "[s]ection 7 is also implicated when the state restricts individuals' security of the person by interfering with, or removing from them, control over their physical or mental integrity". There is no question, then, that personal autonomy, at least with respect to the right to make choices concerning one's own body, control over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person, at least to the extent of freedom from criminal prohibitions which interfere with these. . . .
>
> [¶ 102] In my view, Parker has also established that the marihuana prohibition infringed the second aspect of liberty that I have identified – the right to make decisions that are of fundamental personal importance. As I have stated, the choice of medication to alleviate the effects of an illness with life-threatening consequences is a decision of fundamental personal importance. In my view, it ranks with the right to choose whether to take mind-altering psycho-tropic drugs for treatment of mental illness, a right . . . ranked as "fundamental and deserving of the highest order of protection" in *Fleming v. Reid* (1991). . . .

Also within the last five years, Holland and England have recognized the medical value of cannabis and supported research and public distribution systems.

The Ontario court's approach underscores the utter implausibility of the government's position here: The Canadian government has no trouble prosecuting recreational marijuana cases despite a fundamental right to medical use, but the United States government thinks otherwise. The law enforcement interest, if it exists at all (and, in light of *Winston v. Lee* and *Lawrence v. Texas*, we do not agree that it does), is not remotely or legitimately limited or harmed by medical use legislation. They can co-exist, and they do

in California. As happened here, the Butte County Sheriff's Office was ready to leave Respondent Monson's six marijuana plants alone, fully recognizing her state right to possess them, but the DEA thought otherwise and destroyed them. *Raich v. Ashcroft,* 352 F.3d 1222, 1225-26 (9th Cir. 2003).

E. Civilized notions of personal liberty require this Court to recognize a constitutional right to state-chartered doctor-supervised treatment that is superior to any interest in federal prohibition

Fundamental notions of personal liberty under our scheme of constitutional government and federalism require this Court to recognize that, when a state has explicitly permitted its citizens the medical use of cannabis when doctor and patient agree, there is a fundamental constitutional right to the use of medical cannabis, free from unreasonable federal interference.

IV. Any claim that federal drug law enforcement is harmed by the California Compassionate Use Act of 1996 is untenable

Proposition 215, the California Compassionate Use Act of 1996, has had no material effect on the federal government's law enforcement machinery. Until California began its Compassionate Use Act, the federal government never wasted the time and resources of the DEA and the U.S. Attorney's Offices on such small cases. Arrests, searches and seizures, and prosecutions by the federal government in the face of the California Compassionate Use Act are brought merely to show California voters "who is the boss" by showing that the federal government is fighting the "war on drugs," ignoring the fact that the chronically ill in California are the casualties in this war. The federal government's resources are better spent on other aspects of the "war on drugs" where it can claim that it really believes a drug is a danger to society.

All states and federal government will continue to fight the "war on drugs," notwithstanding Proposition 215 and the laws of the nine other states legitimizing medicinal use of cannabis. California continues to vigorously prosecute marijuana possession cases that do not involve legitimate medical uses. *See* Brief of Reason Foundation as *Amicus Curiae* in Support of Respondents.

The federal spending on the war on drugs has increased seven-fold in 15 years,[35] and the number of people incarcerated for drug crimes has grown 1,000% in twenty years, including California under Proposition 215.[36] The war on drugs, however, has done absolutely nothing to prevent teenagers from experimenting with cannabis.[37] The government's ability to prosecute those who import, grow, and deal marijuana for profit has been unimpeded by Proposition 215 and the laws of the other nine states recognizing medical cannabis. This will not change, and the sky will not fall if Respondents prevail.

The federal government virtually *never* prosecutes cases involving individual users of small amounts of marijuana. The states do because it falls within *their* police power and *not* the federal government's. This fact only adds to the conclusion that is no meaningful federal interest involved in interfering with the vote of the citizens of California in adopting Proposition 215. Casualties

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[35] The Office of National Drug Control Policy FY 1985 budget was $2.7 billion. The FY 2001 proposed budget is $19.2 billion. THE NATIONAL DRUG CONTROL STATEGY: FY 2001, BUDGET SUMMARY 2000 ANNUAL REPORT, Table 3 <http://www.whitehousedrugpolicy.gov/policy/budget00/exec_summ.html#table3>.

[36] There are now more than 450,000 drug offenders behind bars, a total nearly equal to the entire U.S. prison population of 1980. SCHIRALDI & ZIEDENBERG, POOR PRESCRIPTION: THE COST OF IMPRISONING DRUG OFFENDERS IN THE UNITED STATES, Justice Policy Institute (2000).

[37] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, MONITORING THE FUTURE NATIONAL RESULTS ON ADOLESCENTS' DRUG USE: OVERVIEW OF KEY FINDINGS, Table 9: Long-Term Trends in Perceived Availability of Drugs by Twelfth Graders: Marijuana 1975-2000 (2001).

in the "war on drugs" should not be the chronically and terminally ill who are aided by medical use of cannabis.

If our Constitution means anything, it should mean that "the war on drugs" cannot be made to be a war on the quality of life of the chronically or terminally ill. Sadly, for the sake of public respect for our government, the government believes in and promotes a constitutional regime that enables the federal government to enforce its policies which only serve to enhance patient pain contrary to state law and in denigration of the principles embodied in the Ninth and Tenth Amendments and to elementary notions of federalism. This Court must reject any such a view of the federal law and the Constitution that violates the rights of both citizens and the states to enact laws for their common good where there is no federal interest and where the federal government expressly disclaimed any interest in preemption under 21 U.S.C. § 903.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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APPENDIX A

HEALTH ORGANIZATIONS SUPPORTING IMMEDIATE LEGAL ACCESS TO MEDICAL MARIJUANA AND THEIR POSITION STATEMENTS

International and National Organizations

AIDS Action Council
AIDS Treatment News
American Academy of Family Physicians
American Medical Student Association
American Nurses Association
American Preventive Medical Association
American Public Health Association
American Society of Addiction Medicine
Arthritis Research Campaign (England)
Australian Medical Association (New South Wales) Limited
Australian National Task Force on Cannabis
Belgian Ministry of Health
British House of Lords Select Committee on Science and Technology
British House of Lords Select Committee on Science and Technology (Second Report)
British Medical Association
Canadian AIDS Society (Societe Cannadienne du Sida)
Canadian Special Senate Committee on Illegal Drugs
Dr. Dean Edell (surgeon and nationally syndicated radio host)
Federation of American Scientists
French Ministry of Health
Health Canada
Kaiser Permanente
Lymphoma Foundation of America
Montel Williams MS Foundation
Multiple Sclerosis Society (Canada)
Multiple Sclerosis Society (England)

National Academy of Sciences Institute of Medicine (IOM)
National Association for Public Health Policy
National Nurses Society on Addictions
Netherlands Ministry of Health
New England Journal of Medicine
New South Wales (Australia) Parliamentary Working Party on the Use of Cannabis for Medical Purposes
Dr. Andrew Weil (nationally recognized professor of internal medicine)

State and Local Organizations

Alaska Nurses Association
Being Alive: People with HIV/AIDS Action Committee (San Diego, CA)
California Academy of Family Physicians
California Nurses Association
California Pharmacists Association
Colorado Nurses Association
Florida Governor's Red Ribbon Panel on AIDS
Florida Medical Association
Hawaii Nurses Association
Medical Society of the State of New York
Mississippi Nurses Association
New Mexico Nurses Association
New York County Medical Society
New York State Nurses Association
North Carolina Nurses Association
Report of the Medical Marijuana Study Committee (Vermont)
Rhode Island Medical Society
Rhode Island State Nurses Association
San Francisco Mayor's Summit on AIDS and HIV
San Francisco Medical Society
Virginia Nurses Association
Whitman-Walker Clinic (Washington, DC)
Wisconsin Nurses Association

Additional AIDS Organizations

(The following organizations are signatories to a February 17, 1999 letter to the US Department of Health petitioning the federal government to "make marijuana legally available . . . to people living with AIDS.")

AIDS Action Council
AIDS Foundation of Chicago
AIDS National Interfaith Network (Washington, DC)
AIDS Project Arizona
AIDS Project Los Angeles
Being Alive: People with HIV/AIDS Action Committee (San Diego, CA)
Boulder County AIDS Project (Boulder, CO)
Colorado AIDS Project
Center for AIDS Services (Oakland, CA)
Health Force: Women and Men Against AIDS (New York, NY)
Latino Commission on AIDS
Mobilization Against AIDS (San Francisco, CA)
Mothers Voices to End AIDS (New York, NY)
National Latina/o Lesbian, Gay, Bisexual And Transgender Association
National Native American AIDS Prevention Center
Northwest AIDS Foundation
People of Color Against AIDS Network (Seattle, WA)
San Francisco AIDS Foundation
Whitman-Walker Clinic (Washington, DC)

Other Health Organizations

(The following organizations are signatories to a June 2001 letter to the US Department of Health petitioning the federal government to "allow people suffering from serious illnesses . . . to apply to the federal government

for special permission to use marijuana to treat their symptom")

Addiction Treatment Alternatives
AIDS Treatment Initiatives (Atlanta, GA)
American Public Health Association
American Preventive Medical Association
Bay Area Physicians for Human Rights
(San Francisco, CA)
California Legislative Council for Older Americans
California Nurses Association
California Pharmacists Association
Embrace Life (Santa Cruz, CA)
Gay and Lesbian Medical Association
Hawaii Nurses Association
Hepatitis C Action and Advisory Coalition
Life Extension Foundation
Maine AIDS Alliance
Minnesota Nurses Association
Mississippi Nurses Association
National Association of People with AIDS
National Association for Public Health Policy
National Women's Health Network
Nebraska AIDS Project
New Mexico Nurses Association
New York City AIDS Housing Network
New York State Nurses Association
Ohio Patient Network
Okaloosa AIDS Support and Information Services
(Fort Walton, FL)
Physicians for Social Responsibility – Oregon
San Francisco AIDS Foundation
Virginia Nurses Association
Wisconsin Nurses Association

APPENDIX B

No. 03-1454

In The
United States Supreme Court

JOHN ASHCROFT, ATTORNEY GENERAL, *ET AL.*,
Petitioner,

v.

ANGEL MCCLARY RAICH, *ET AL*,
Respondents.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Ninth Circuit

DECLARATION OF LESTER GRINSPOON, M.D., IN SUPPORT OF THE BRIEF OF *AMICI CURIAE* NATIONAL ORGANIZATION FOR THE REFORM OF MARIJUANA LAWS (NORML) AND THE NORML FOUNDATION

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October 2004

I, LESTER GRINSPOON, M.D., declare:

1. I am an Associate Professor of Psychiatry (emeritus), at Harvard Medical School in Boston, Massachusetts, where I have taught for more than 35 years. I am also the Founding Editor of The Harvard Mental Health Letter. My area of research is psychoactive drugs. I am particularly interested in the medicinal properties of cannabis. For the Court's convenience, where appropriate I have provided footnotes referencing the sources upon which I have relied.

2. I received a Bachelor of Science degree in 1951 from Tufts College and a Doctorate of Medicine in 1955 from Harvard Medical School. I subsequently completed and [sic] internship in medicine at Beth Israel Hospital in Boston, Massachusetts (1955-1956), and a residency in psychiatry at Massachusetts Mental Health Center (1958-1961). I received further training as a field instructor for the National Cancer Institute in Los Angeles, California (1956-1958).

3. Since joining the Harvard Medical School faculty in 1961, I have held numerous positions, including Assistant Clinical Professor, Associate Clinical Professor and Associate Professor at the Harvard Medical School. My other research and teaching appointments include: Assistant in Medicine at the University of Southern California School of Medicine (1956-1958), Director of the Clinical Research Center for the Massachusetts Mental Health Center (1961-1968), Consultant in Psychiatry and Research for Boston State Hospital (1963-1970) and an Examiner for the American Board of Psychiatry and Neurology (1969-1980). I have also held several positions for the American Psychiatric Association such as Vice-Chairperson (1975-1977) and Chairperson for the Council on Research

(1977-1979); Vice-Chairperson (1979-1980) and Chairperson for the Scientific Program Committee (1980-1984).

4. I serve on several professional and community boards. These include many years as a member of the Beneficial Plant Research Association (1980-1984), the Drug Policy Foundation (1987-1995), Physicians for Human Rights (1986-present), the Drug Research Group (1995-present), and Scientific and Policy Advisors of the American Council on Science and Health (1997-present). I recently served as Chairperson for the Board of Directors for the National Organization for the Reform of Marijuana Laws (1993-1995). I was also a faculty member for the Zinberg Center for Addiction Studies in Cambridge, Massachusetts (1993-1996). I am currently on several editorial boards, including the Harvard Health Letter (1990-present), the Journal of Social Pharmacology (1985-present), and Addiction Research (1991-present).

5. I have testified before the National Marijuana Commission and the Subcommittee of the Senate Small Business Committee in 1972, the House Select Committee on Narcotics in 1977, 1979 and 1989, the Controlled Substances Advisory Committee, and the Drug Abuse Advisory Committee in 1978, the Senate Judiciary Committee in 1980, and the House Judiciary Committee, Sub-Committee on Crime in 1997. I am also a frequent presenter at national and international conferences.

6. I have authored and co-authored some 170 articles in scholarly and professional journals, most of which deal with clinical comparisons of drug therapies. I have contributed chapters to medical textbooks, research publications, clinical protocols and conference reports. My work has been published in the *Journal of Clinical Endocrinology and Metabolism, New England*

Journal of Medicine, Journal of the National Cancer Institute, Mental Patients in Transition, Science Digest, Archives of General Psychiatry, Comprehensive Psychiatry, Clinical Medicine, Journal of Psychiatric Research, Psychosomatic Medicine, Diseases of the Nervous System, American Journal of Psychiatry, Scientific America, Psychopharmacologica, International Journal of Psychiatry, Encyclopedia of Science and Technology, International Narcotic Report, New York Law Journal, Journal of Consulting and Clinical Psychology, Drug Therapy, World Journal of Psychosynthesis, Medical Tribune, Contemporary Drug Problems, Social Science and Medicine, Villanova Law Review, Congressional Digest, Biological Psychiatry, The Sciences, Journal of Ethnopharmacology, Handbook on Drug Abuse, The Hastings Center Report, Harvard Mental Health Letter, Harper's, Nova Law Review, New Harvard Guide to Psychiatry, Journal of State Government, Cancer Treatment & Marijuana Therapy, Journal of Drug Issues, North Carolina Journal of International Law & Commercial Regulation, Encyclopedia of Human Biology, Drugs, Society and Behavior, Journal of American Medical Association, University of West Los Angeles Law Review, and *Journal of Psychoactive Drugs.*

7. I have authored and co-authored 12 books, several of which deal with the history and medical use of cannabis. These books include *Marijuana Reconsidered* (Harvard University Press, 2d ed. 1977), *Psychedelic Drugs Reconsidered* (Basic Books, 2d ed. 1981), *Psychedelic Reflections* (Human Sciences Press, 1982), *The Long Darkness: Psychological and Moral Perspectives on Nuclear Winter* (Yale University Press, 1986), and *Marijuana, the Forbidden Medicine* (Yale University Press, Revised Edition, 1997).

8. Based on my research, I have found that cannabis is remarkably safe. Although not harmless, it is surely

less toxic than most of the conventional medicines it could replace if it were legally available. Despite its use by millions of people over thousands of years, cannabis has never caused an overdose death. The most serious concern is respiratory damage from smoking, but that can easily be addressed by increasing the potency of cannabis and by making use of the technology to separate the particulate matter in marijuana smoke from its active ingredients, the cannabinoids (through devices known as vaporizers). Once cannabis regains the place in the U.S. Pharmacopoeia that it lost in 1941 after the passage of the Marihuana Tax Act (1937), it will be among the least toxic substances in that compendium. Right now the greatest danger in using cannabis medically is the illegality that imposes a great deal of anxiety and expense on people who are already suffering.

9. I have done extensive research on the history of the use of cannabis for medical purposes, as well as its legal regulation in the United States. The marijuana, cannabis, or hemp plant is one of the oldest psychoactive plants known to humanity. A native plant of central Asia, cannabis may have been cultivated as much as ten thousand years ago. It was certainly cultivated in China by 4000 B.C. and in Turkestan by 3000 B.C. It has long been used as a medicine in India, China, the Middle East, Southeast Asia, South Africa, and South America. The first evidence of the medical use of cannabis was published during the reign of the Chinese Emperor Chen Nun five thousand years ago. Cannabis was recommended for, among other things, malaria and rheumatic pains. Another Chinese herbalist recommended a mixture of hemp, resin, and wine as an analgesic during surgery. Hemp was also noted as a remedy by Galen and other physicians of the classical and Hellenistic eras, and it was highly valued in Europe.

10. Between 1840 and 1900, more than one hundred papers on the therapeutic uses of cannabis were published in American and European medical journals. It was recommended as an appetite stimulant, muscle relaxant, analgesic, sedative, anticonvulsant, and as a treatment for opium addiction. A professor at the Medical College of Calcutta, W.B. O'Shaughnessy, was the first Western physician to observe the use of cannabis as a medicine. He gave cannabis to animals, satisfied himself that it was safe, and began to use it with patients suffering from rabies, rheumatism, epilepsy, and tetanus. In a report published in 1839, he wrote that he found tincture of hemp (a solution of cannabis in alcohol, taken orally) to be an effective analgesic. He was also impressed with its muscle relaxant properties and called it "an anticonvulsive remedy of the greatest value." In 1890, J.R. Reynolds, a British physician, summarized thirty years of experience with *Cannabis indica,* finding it valuable in the treatment of various forms of neuralgia, including the tic douloureux (a painful facial neurological disorder), and added that it was useful in preventing migraine attacks. He also found it useful for certain kinds of epilepsy, for depression, and sometimes for asthma and dysmenorrhea.

11. The medical use of cannabis was in decline by 1890. It was believed that the potency of cannabis preparations was too variable, and that individual responses to orally ingested cannabis seemed erratic and unpredictable. Another reason for the neglect of research on the analgesic properties of cannabis was the generally increased use of opiates after the invention of the hypodermic syringe in the 1850s allowed soluble drugs to be injected for fast pain relief; hemp products are insoluble in water and so cannot easily be administered by injection. Toward the end of the nineteenth century, the development of such synthetic drugs as

aspirin, chloral hydrate, and barbiturates, also contributed to the decline of cannabis as a medicine. But these new drugs had, and still have today, striking disadvantages. More than a thousand people die from aspirin-induced bleeding each year in the United States, and barbiturates are, of course, far more dangerous.

12. Cannabis use in the United States was not particularly a matter of state or federal regulation until 1915, when California, prohibited marijuana possession or sale. In 1930, the year in which the Federal Bureau of Narcotics was founded, only sixteen states had laws prohibiting the use of cannabis. Sociologists have speculated that pressure from the liquor lobby figured among the more subtle factors in this sudden legal onslaught. More important, lack of scientific understanding concerning the effects of cannabis enabled the unsubstantiated statements of the Federal Bureau of Narcotics to go substantially unchallenged. The Marijuana Tax Act of 1937 was the culmination of a series of efforts on the part of the Federal Bureau of Narcotics to generate anti-marijuana legislation.

13. One might have expected physicians looking for better analgesics and hypnotics to turn to cannabinoid substances, but the Marijuana Tax Act of 1937 undermined any such experimentation. The Marijuana Tax Act of 1937 imposed a transfer tax upon certain dealings with marijuana. The Marijuana Tax Act of 1937 provided that anyone who imports, manufactures, produces, compounds, sells, deals in, dispenses, prescribes, administers, or gives away marijuana was required to register, record transactions and pay special taxes depending on the defined purposes. Those who failed to comply were subject to large fines or prison for tax evasion. Although it was ostensibly designed to prevent non-medical use of cannabis, the Marijuana Tax Act of 1937 made cannabis so difficult to obtain,

that cannabis was removed from the United States Pharmacopoeia and National Formulary in 1941. The Boggs Act of 1951 established mandatory prison terms and large fines for violation of any federal drug law, and the Narcotic Control Act of 1956 strengthened those penalties.

14. In the 1960's however, the public began to rediscover the medical value of cannabis, as letters appeared in lay publications from people who had learned that it could relieve their asthma, nausea, muscle spasms, or pain and wanted to share that knowledge with readers who were familiar with the drug. Meanwhile, legislative concern about recreational use of cannabis increased, and in 1970 Congress passed the Comprehensive Drug Abuse Prevention and Control Act (also called the Controlled Substances Act), which assigned psychoactive drugs to five schedules and placed cannabis in Schedule I, the most restrictive.

15. A few patients have been able to obtain medical cannabis legally in the past twenty years. Beginning in the 1970s, thirty-five states passed legislation that would have permitted medical use of cannabis but for the federal law. Several of those states actually established special research programs, with the permission of the federal government, under which patients who were receiving cancer chemotherapy would be allowed to use cannabis. These projects demonstrated the value of both smoked marijuana and oral THC (tetrahydrocannabinol). The FDA approved oral THC (Marinol) as a prescriptive medicine in 1986. In 1976, the federal government introduced the Individual Treatment Investigational New Drug Program (commonly referred to as the Compassionate IND), which provided cannabis to a few patients whose doctors were willing to undergo the paperwork-burdened and time-consuming application process. About three-dozen

patients eventually received cannabis before the program was discontinued in 1992, and six survivors are still receiving it – the only persons in the country for whom it is not a forbidden medicine.

16. The most effective spur to the movement for medical marijuana came from the discovery that it could prevent the AIDS wasting syndrome. It is not surprising that the Physicians Association for AIDS Care was one of the medical organizations that endorsed the California initiative prohibiting criminal prosecution of medical marijuana users.

17. I have conducted an extensive review of the literature concerning medical uses of cannabis and I am familiar with studies on the topic. Review of medical literature is a commonly used research tool. I have also studied clinically many patients who have used cannabis for the relief of a variety of symptoms; this clinical experience forms the basis of my book, *Marihuana, The Forbidden Medicine*. In my book I provide first-person accounts of the ways that cannabis alleviates symptoms of cancer chemotherapy, multiple sclerosis, osteoarthritis, glaucoma, AIDS and depression, as well as symptoms of less common disorders such as Crohn's disease, diabetic gastroparesis, and post-traumatic stress disorder. The patient narratives illustrate not only cannabis's therapeutic properties but also the unnecessary further pain and anxiety imposed on sick people who must obtain cannabis illegally.

18. Cannabis has several uses in the treatment of cancer. As an appetite stimulant, it can help to slow weight loss in cancer patients. It may also act as a mood elevator. But the most common use is the prevention of nausea and vomiting associated with cancer chemotherapy. About half of patients treated with anticancer drugs suffer from severe nausea and vomiting, which

are not only unpleasant and painful but a threat to the effectiveness of the therapy. Retching can cause tears of the esophagus and rib fractures, prevent adequate nutrition, and lead to fluid loss. Some patients find the nausea so intolerable they say they would rather die than go on. The antiemetics most commonly used in chemotherapy are metoclopramide (Reglan), the relatively new ondansetron (Zofran), and the newer granisetron (Kytril). Unfortunately, for many cancer patients these conventional antiemetics do not work at all or provide little relief.

19. The suggestion that cannabis might be used in the treatment of cancer arose in the early 1970s when some young patients receiving cancer chemotherapy found that marijuana smoking reduced their nausea and vomiting. In one study of 56 patients who got no relief from standard antiemetic agents, 78% became symptom-free when they smoked marijuana[1]. Oral tetrahydrocannibinol (THC) has proved effective where the standard drugs were not,[2] but smoking generates faster and more predictable relief because it raises THC concentration in the blood more rapidly to the needed level. Also, it may be hard for a nauseated patient to take oral medicine. In fact, there is strong evidence that most patients suffering from nausea and vomiting prefer smoked marijuana to oral THC.

20. Oncologists may have been ahead of other physicians in recognizing the therapeutic potential of cannabis. In the spring of 1990, two investigators randomly

[1] Vinciguerra, V., et al. Inhalation Marijuana as an antiemetic for cancer chemotherapy. *New York State Journal of Medicine* 1988; 88:525-527.

[2] Sallan, S.E., et al. Antiemetic effect of delta-9-tetrahydrocannibinol in patients receiving cancer chemotherapy. *New England Journal of Medicine* 1975; 293:795-797.

selected more than 2,000 members of the American Society of Clinical Oncology and mailed them an anonymous questionnaire to learn their views on the use of cannabis in cancer chemotherapy. Almost half of them responded. Although the investigators acknowledged that this group was self-selected and there might be a response bias, their results provide a rough estimate of the views of specialists on the use of Marinol (dronabinol, oral synthetic THC), and smoked marijuana. Only 43% said the available legal antiemetic drugs (including Marinol) provided adequate relief to all or most of their patients, and only 46% said the side effects of these drugs were rarely a serious problem. Forty-four percent had recommended the illegal use of cannabis to at least one patient, and half would prescribe it to some patients if it were legal. On average, they considered smoked marijuana more effective than Marinol and roughly as safe.[3]

21. Cannabis is also useful in the treatment of glaucoma, the second leading cause of blindness in the United States. In this disease, fluid pressure within the eyeball increases until it damages the optic nerve. About a million Americans suffer from the form of glaucoma (open angle) treatable with cannabis. Glaucoma is treated chiefly with eyedrops containing betablockers such as timolol (Timoptic), which inhibits the activity of epinephrine (adrenaline). They are effective but may have serious side effects such as inducing depression, aggravating asthma, slowing the heart rate, and increasing the risk of heart failure. Cannabis causes a dose-related, clinically significant drop in intraocular

[3] Doblin R. Kleiman M. Marihuana as anti-emetic medicine: a survey of oncologists' attitudes and experiences. *Journal of Clinical Oncology* 1991; 9:1275-80.

pressure that lasts several hours in both normal subjects and those with abnormally high ocular tension produced by glaucoma. Oral or intravenous THC has the same effect, which seems to be specific to cannabis derivatives rather than simply a result of sedation. Cannabis does not cure the disease, but it can retard the progressive loss of sight when conventional medication fails and surgery is too dangerous.[4]

22. About 15-20% of epileptic patients do not get much relief from conventional anticonvulsant medications. Cannabis has been explored as an alternative at least since 1975 when a case was reported in which marijuana smoking, together with the standard anticonvulsants phenobarbital and diphenylhydantoin, was apparently necessary to control seizure in a young epileptic man.[5] The cannabis derivative that is most promising as an anticonvulsant is cannabidiol. In one controlled study, cannabidiol in addition to the prescribed anticonvulsants produced improvement in seven patients with grand mal convulsions; three showed great improvement. Of eight patients who received a placebo instead, only one improved.[6] There are patients suffering from both grand mal and partial seizure disorders who find that smoked marijuana allows them to lower the doses of conventional anticonvulsant medications or to dispense with them altogether. Furthermore, anticonvulsants have many

[4] Hepler. R.S., et al. Ocular Effects of Marihuana Smoking. M.C. Braude, S. Szara (eds.). *The Pharmacology of Marihuana*. New York: Raven Press, 1976.

[5] Consroe, Paul F., et al. Anticonvulsant nature of Marihuana smoking. *Journal of the American Medical Association* 1975; 234-306-307.

[6] Cunha, J.M., et al. Chronic administration of cannabidiol to healthy volunteers and epileptic patients. *Pharmacology* 1980; 21:175-185.

potentially serious side affects, including bone softening, anemia, swelling of the gums, double vision, hair loss, headaches, nausea, decreased libido, impotence, depression and psychosis. Overdoses or idiosyncratic reactions may lead to loss of motor coordination, coma or even death.

23. There are many case reports of cannabis smokers using the drug to reduce pain: post-surgery pain, headache, migraine, menstrual cramps, and so on. Ironically, the best alternative analgesics are the potentially addictive and lethal opioids. In particular, cannabis is becoming increasingly recognized as the most effective treatment for the pain that accompanies muscle spasm, which is often chronic and debilitating, especially in paraplegics, quadriplegics, or other victims of traumatic nerve injury, and people suffering from multiple sclerosis or cerebral palsy. Many of them have discovered that cannabis not only allows them to avoid the risks of other drugs, but also reduces muscle spasms and tremors; sometimes they are even able to leave their wheel chairs.[7]

24. One of the most common causes of chronic pain is osteoarthritis, which is usually treated with synthetic analgesics. The most widely used of these drugs – aspirin, acetaminophen (Tylenol), and nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and naproxen – are not addictive, but they are insufficiently powerful. Furthermore, they have serious side effects. Stomach bleeding and ulcer induced by aspirin and NSAIDs are the most common serious adverse drug reactions reported in the United States, causing an estimated 7,000 deaths each year. Acetaminophen

[7] Petro, D.J. Ellenberger, C., Treatment of human spacticity with delta-9-tetrahyrdrocannabinol. *Journal of Clinical Pharmacology* 1981; 21:413-416.

can cause liver damage or kidney failure when used regularly for long periods of time; a recent study suggests its chronic use may account for 10% of all cases of end-stage renal disease, a condition that requires dialysis or a kidney transplant.[8] Cannabis, as I pointed out earlier, has never been shown to cause death or serious illness. The University of Iowa conducted a study of cannabis for the relief of pain. Researchers gave oral THC or placebo at random to hospitalized cancer patients who were in severe pain. The THC relieved pain for several hours in doses as low as 5-10 mg, and for even longer at 20 mg. At this dose and in this setting, THC proved to be a sedative as well. It had fewer side effects than other commonly used analgesics.[9]

25. Oncologists are legally permitted to administer the synthetic THC (Marinol) orally in capsule form. But inhaled cannabis may be necessary for several reasons. For one thing, oral THC is subject to the variances of bioavailability. This means that two patients who take the same amount may also absorb different proportions of the dose, and a given patient may respond differently on different days, depending on the condition of the intestinal tract and other factors. Furthermore, the effects of smoked cannabis are perceived almost immediately, so patients can smoke slowly and take only what they need for a therapeutic effect. Patients who swallow Marinol may discover after an hour or so that they have taken too much for

[8] Perneger, T.V., Whelton, P., Klag, M.J. Risk of kidney failure associated with the use of acetaminophen, aspirin, and nonsteroidal anti-inflammatory drugs. *New England Journal of Medicine* 1994; 331:25:1675-1679.

[9] R. Noyes, S.F. Brunk, D.A. Baram, and A. canter, "Analgesic Effects of Delta-9-tetrahydrocannabinol, "*Journal of Clinical Pharmacology* 15 (February-March 1975): 139-143.

comfort or not enough to relieve their symptoms. In any case, a patient who is severely nauseated and constantly vomiting may find it almost impossible to keep the capsule down. Furthermore, Marinol makes some patients anxious and uncomfortable.

26. In theory, all the therapeutic properties of cannabis could be used if individual cannabinoids in addition to THC were isolated and made available separately as medicines. But this would be an enormously complicated procedure. Research sponsors would have to determine the therapeutic potential and evaluate the safety of sixty or more substances, synthesize each one found to be useful, and package it as a pill or aerosol. As some of these substances probably act synergistically, it would also be necessary to look at various combinations of them. However, no drug company would provide the resources needed for such a project because cannabis cannot be patented. It is a plant material containing many chemicals rather than a single one and no drug in the present pharmacopoeia is delivered by smoking.

27. About 500,000 have died of AIDS. Nearly 900,000 are infected with HIV, and about 400,000 have AIDS. Although the spread of AIDS has slowed down among homosexual men, the reservoir is so huge that the number of cases is sure to grow. Women and children as well as both heterosexual and homosexual men are now being affected; the disease is spreading most rapidly among intravenous drug abusers and their sexual partners. The disease can be attacked with anti-viral drugs, of which the best known are zidovudine (AZT) and protease inhibitors. Unfortunately, these drugs sometimes cause severe nausea that heightens the danger of semi-starvation for patients who are already suffering from nausea and losing weight because of the illness – a condition sometimes called the AIDS wasting syndrome. Cannabis is particularly useful for

patients who suffer from AIDS because it not only relieves the nausea but also retards weight loss by enhancing appetite. In one study the body weight and caloric intake of twenty-seven marijuana users and ten control subjects were compared for twenty-one days on a hospital research ward. The marijuana smokers ate more than the controls and gained weight; the controls did not. When they stopped smoking marijuana, they immediately started to eat less.[10] When it helps patients regain lost weight, it can prolong life. Although Marinol has been shown to relieve nausea and retard or reverse weight loss in patients with HIV infection, most patients prefer smoked cannabis. Cannabis is more effective and has fewer unpleasant side effects, and the dosage is easier to adjust. Many patients report that cannabis provides an appetite and pain relief without the semi-comatose effect of narcotics.

28. Opponents of medical cannabis often object that the evidence of its usefulness, although strong, comes only from case reports and clinical experience. It is true that there are, as yet, few double-blind controlled studies meeting the standards of the Food and Drug Administration, chiefly because legal, bureaucratic, and financial obstacles have been constantly put in the way. However we know more about cannabis than about most prescription drugs. Furthermore, individual therapeutic responses are often obscured in group experiments, and case reports and clinical experience are the source of much of our knowledge of drugs. As Dr. Louis Lasagna has pointed out, controlled experiments were not needed to recognize the therapeutic

[10] I. Greenberg, J. Kuelmle, J.H. Mendelson, and J.G. Bernstein, "Effects of Marijuana Use of Body Weight and Caloric Intake in Humans," *Journal of Psychopharmacology* (Berlin) 49 (1976): 79-84.

potential of chloral hydrate, barbiturates, aspirin, insulin or penicillin.[11] Nor was that the way we learned about the use or propranolol for hypertension, diazepam for status epilepticus and imipramine for enuresis; these drugs had originally been approved for other purposes.

29. In the experimental method known as the single patient randomized trial, active and placebo treatments are administered randomly in alteration or succession. The method is often used when large-scale controlled studies are inappropriate because the disorder is rare, the patient is atypical or the response to treatment is idiosyncratic.[12] Several patients have told me that they assured themselves of cannabis's effectiveness by carrying out such experiments on themselves, alternating periods of cannabis use with periods of abstention. I am convinced that the medical reputation of cannabis is derived partly from similar "experiments" conducted by many other patients.

30. Some physicians may regard it as irresponsible to advocate use of a medicine on the basis of case reports, which are sometimes disparaged as merely "anecdotal" evidence which counts apparent successes and ignores apparent failures. This would be a serious problem if cannabis were a dangerous drug. The years of effort devoted to showing that cannabis is exceedingly dangerous have proved the opposite. It is safer,

[11] Lasagna, L. Clinical trials in the natural environment. C. Stiechele, W. Abshagan, J. KichWeser (cds). *In Drugs Between Research and Regulations.* New York: Springer-Verlag, 1985:45-49.

[12] Larson, E.B. N-og-1 clinical trials: A technique for improving medical therapeutics. *Western Journal of Medicine* 1990; 152:52-56; Guyatt, G.H. Keller, J.L., Jaschke, R., et al. The N-of-1 randomized controlled trial: Clinical usefulness. *Annals of Internal Medicine* 1990; 112:293-299.

with fewer serious side effects, than most prescription medicines, and far less addictive or subject to abuse than many drugs now used as muscle relaxants, hypnotics and analgesics.

31. Based on the best available medical information, it is evident that cannabis should be made available even if only a few patients could get relief from it, because the risks are so small. For example, as I mentioned, many patients with multiple sclerosis find that cannabis reduces their muscle spasms and pain. A physician may not be sure that such a patient will get more relief from cannabis than from the standard drugs baclofen, dantrolene, and diazepam – all of which are potentially dangerous or addictive –but it is most certain that a serious toxic reaction to cannabis will not occur. Therefore the potential benefit is much greater than any potential risk.

32. During the past few years, the medical use of cannabis have become increasingly clear to many physicians and patients, and the number of people with direct experience of these uses has been growing. Therefore, the discussion is now turning from whether cannabis is an effective medicine to how it should be made available.

33. The government's position that cannabis has no accepted medical use is not rational, given the wealth of information confirming that cannabis is an effective medicine. Moreover, in my view, the government has long obstructed efforts to conduct research concerning cannabis. Had the United States government not stood in the way of such research, I believe that we would be at least 50 years ahead of where we are today in making cannabis available to persons who need it for medical reasons.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 8th day of October, 2004, at Wellesley, Massachusetts 02181.

/s/ Lester Grinspoon
LESTER GRINSPOON, MD

SUPREME COURT, U.S.
FILED
AUG 11 2004
OFFICE OF THE CLERK

No. 03-1454

In the

Supreme Court of the United States

JOHN D. ASHCROFT, Attorney General, et al.,

Petitioners,

v.

ANGEL McCLARY RAICH, et al.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF NEITHER PARTY

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QUESTION PRESENTED

Does the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, exceed Congress' power under the Commerce Clause as applied to the intrastate cultivation and possession of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use?

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IDENTITY AND INTEREST OF AMICUS CURIAE

Under Supreme Court Rule 37,[1] Pacific Legal Foundation (PLF) respectfully submits this brief amicus curiae in support of neither party on the merits. Written consent was granted by counsel for all parties and lodged with the clerk of this Court.

PLF was founded over 30 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide. PLF advocates limited government, individual rights, and free enterprise. PLF has participated in numerous cases addressing the balance of power between the states and the federal government, including this Court's landmark Commerce Clause cases on which this case turns. For example, PLF participated as amicus curiae in *United States v. Lopez,* 514 U.S. 549 (1995), *United States v. Morrison,* 529 U.S. 598 (2000), *Jones v. United States*, 529 U.S. 848 (2000), and *Solid Waste Agency of Northern Cook County v. Army Corps of Engineers,* 531 U.S. 159 (2001).

Amicus Curiae will discuss the development of the *Lopez* "substantial effects" standard and the limits of the commerce power. PLF takes no position on the validity of the Controlled Substance Act (CSA) or on the medicinal use of marijuana.

INTRODUCTION

This Court has recognized three categories of activity that Congress is empowered to regulate under the Commerce Clause. First, Congress has authority to regulate the use of the channels of interstate commerce. *Lopez*, 514 U.S. at 558.

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[1] Pursuant to Supreme Court Rule 37.6, Amicus Curiae affirms that no counsel for any party authored any part of this brief and no person or entity made a monetary contribution for the preparation or submission of this brief.

Second, Congress may "regulate and protect the instrumentalities of interstate commerce, or persons or things in interstate commerce." *Id.* And third, Congress is authorized to regulate those activities "that substantially affect interstate commerce." *Id.* at 559. The "substantial effects" category is the most far reaching of the three and the most likely basis for determining the validity of the Controlled Substances Act, as applied to the intrastate, noncommercial cultivation, possession, and distribution of marijuana for purported medicinal purposes.

In *Lopez* and *Morrison*, this Court established a simple framework for analyzing Commerce Clause enactments that are based on the regulation of activities that substantially affect interstate commerce. However, the lower courts have generally not been faithful in applying this framework to various federal statutes, such as the Hobbs Act, the Endangered Species Act, and the Clean Water Act.

To avoid invalidating a federal act or limiting Congress' power under the Commerce Clause, the lower courts typically misapply *Lopez* and *Morrison* by aggregating intrastate, noncommercial activities to find substantial effects on interstate commerce. Or, they simply declare that the challenged statute implements an important national scheme substantially affecting interstate commerce which requires the regulation of individual intrastate, noncommercial activities. The Ninth Circuit decision in this case is a notable exception. Whatever this Court decides on the merits of this case, it should reflect the fact that

> in those cases where [this Court has] sustained federal regulation of intrastate activity based upon the activity's substantial effects on interstate commerce, the activity in question has been some sort of economic endeavor.

Morrison, 529 U.S. at 611.

We, therefore, urge this Court to uphold the Commerce Clause limits this Court outlined in *Lopez* and *Morrison* and not authorize the regulation of intrastate, noncommercial activities to broaden the scope of the federal commerce power.

SUMMARY OF THE ARGUMENT

In *Wickard v. Filburn*, 317 U.S. 111 (1942), this Court found that the federal government could regulate local economic activity such as excess wheat grown on a farm for sale and farm consumption, even though the wheat by itself had only a *de minimis* effect on interstate commerce. This Court reasoned that federal regulation of such wheat was a necessary part of a federal economic program to support national and international wheat markets in that homegrown wheat could, in the aggregate, substantially influence price and market conditions. Under this *Wickard* aggregation principle, federal regulatory power under the Commerce Clause greatly expanded, allowing federal regulation of just about anything. *See* Richard A. Epstein, *Propter Honoria Respectum, Constitutional Faith and the Commerce Clause*, 71 Notre Dame L. Rev. 167, 188-89 (1996).

Two recent decisions of this Court, however, attempted to limit federal regulatory power under the Commerce Clause generally and *Wickard* specifically. In *Lopez* and *Morrison*, this Court invalidated federal laws that attempted to regulate wholly intrastate noneconomic activities that had, at best, only attenuated effects on interstate commerce. These cases both turned on the nature of the activity: "[A] fair reading of *Lopez* shows that the noneconomic, criminal nature of the conduct at issue was central to our decision in that case . . . . 'Even *Wickard*, which is perhaps the most far reaching example of Commerce Clause authority over intrastate activity, involved economic activity . . . .'" *Morrison*, 529 U.S. at 610.

In *Lopez*, this Court struck down the Gun Free School Zones Act because the regulated activity—possession of a gun

in a school zone—had nothing to do with economic activity and did not substantially affect interstate commerce. In *Morrison*, this Court invalidated a provision of the Violence Against Women Act that allowed victims of "gender-motivated violence" to sue in federal court. This Court found that physical attacks by one person against another, a wholly intrastate activity, was not economic activity on its face and isolated events could not be aggregated to find substantial effects on interstate commerce.

Both *Lopez* and *Morrison* strongly affirmed that federal power under the Commerce Clause has inherent limits designed to prevent the federal government from becoming a government of general powers, like the states. To protect the "distinction between what is truly national and what is truly local," *Lopez*, 514 U.S. at 567-68, "first principles" require that Commerce Clause enactments actually govern interstate commerce.

But "first principles" are often ignored in the courts below, notwithstanding the pronouncements of this Court in *Lopez* and *Morrison*. Therefore, this Court should unambiguously declare that Congress has no power to regulate intrastate, noncommercial endeavors as activities that substantially affect interstate commerce.

ARGUMENT

I

THE MODERN "SUBSTANTIAL EFFECTS" STANDARD LIMITS THE COMMERCE POWER TO ECONOMIC ACTIVITY

This Court has relied on "substantial effects" to uphold a variety of laws under the Commerce Clause, but three cases are noteworthy for their expansive application of the commerce power. *National Labor Relations Board v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937), *United States v. Darby*, 312 U.S. 100 (1941), and *Wickard v. Filburn* represent the outer

limits of Congress' authority to regulate under the Commerce Clause.

In the first case, the Jones & Laughlin Steel Corporation was charged with unfair labor practices under the National Labor Relations Act when the corporation apparently discharged certain employees because of their union affiliation. As a defense, Jones & Laughlin Steel argued that the Act was constitutionally infirm because it was not directed at commerce but was a gambit aimed at subjecting all industrial labor relations to federal control without regard to the effects on interstate commerce. *See Jones & Laughlin Steel*, 302 U.S. at 29.

To determine the object of the Act, this Court looked to the statutory language itself and observed that the Act empowered the National Labor Relations Board "to prevent any person from engaging in any unfair labor practice . . . affecting commerce." *Id.* at 30. The Act, in turn, defined "commerce" in the traditional sense to mean "trade, traffic, commerce, transportation, or communication among the several states." *Id.* at 31. The Act went further and also defined the term "affecting commerce."

> The term "affecting commerce" means in commerce, or burdening or obstructing commerce or the free flow of commerce, or having led or tending to lead to a labor dispute burdening or obstructing commerce or the free flow of commerce.

Id.

Because the National Labor Relations Act explicitly limited the Board's jurisdiction to only those labor practices actually "affecting commerce," this Court found the Act was a valid Commerce Clause enactment. By "its terms," this Court noted, the Act does "not impose collective bargaining upon all industry regardless of effects upon interstate or foreign

commerce." *Id.* Rather, this Court found, "[i]t purports to reach only what may be deemed to burden or obstruct that commerce, and thus qualified, it must be construed as contemplating the exercise of control within constitutional bounds." *Id.*

The significance of this analysis, as would later become clear in *Lopez* and *Morrison*, lies in this Court's search for a jurisdictional element tying the regulated activity to impacts affecting commerce (so as to limit the scope of the Act to the delegated authority) and this Court's reliance on the terms of the Act itself; on what the Act expressly purports to regulate.

After upholding the Act facially, this Court considered whether the regulated activity was within constitutional bounds as applied in that particular case; that is, whether the unjustified firing of employees would affect (i.e., burden or obstruct) interstate commerce. *Id.* at 32. The record showed that Jones & Laughlin Steel was the fourth largest steel producer in the country with nineteen subsidiaries and integrated operations throughout the nation that included production as well as transportation and sale of products in interstate commerce. *Id.* at 25-26. In counterpoint, however, was the fact that the discharged employees worked only in the local manufacturing plant and were not involved in transporting or selling the product in interstate commerce. *Id.* at 40. According to this Court, this latter fact was not determinative. *Id.* Rather, the case turned on how the stoppage of Jones & Laughlin Steel's manufacturing operations by industrial strife—which the National Labor Relations Act was designed to prevent—would affect interstate commerce. *Id.* at 41.

In considering the matter, this Court relied on what it called the fundamental principle "that the power to regulate commerce is the power to enact 'all appropriate legislation' for its protection and advancement." *Id.* at 37. "That power is plenary," this Court said, "and may be used to protect interstate

commerce 'no matter what the source of the dangers which threaten it.'" *Id.* This Court said further:

> Although activities may be intrastate in character when separately considered, if they have such a close and substantial relation to interstate commerce that their control is essential or appropriate to protect that commerce from burdens and obstructions, Congress cannot be denied the power to exercise that control.

Id.

This statement describes the third category of Commerce Clause enactments—the regulation of activity that substantially affects interstate commerce. As with similar statements of the "substantial effects" category of Commerce Clause regulation, this Court was focused on finding a "close and substantial" impact on interstate commerce and determining whether the regulation was necessary "to protect that commerce."

In view of Jones & Laughlin Steel's far-flung activities, this Court found the stoppage of its intrastate manufacturing operations by industrial strife would have a serious effect on interstate commerce that is direct, immediate, and even catastrophic. *Id.* at 41. When an industry on a national scale makes its relation to interstate commerce a "dominant factor," this Court concluded, Congress may regulate labor relations "to protect interstate commerce from the paralyzing consequences of industrial war." *Id.*

In *United States v. Darby*, this Court upheld the Fair Labor Standards Act, which prohibited the shipment, in interstate commerce, of goods that were produced without compliance with the Act's standards for employee wages and hours. *Darby*, 312 U.S. at 109. This Court determined interstate commerce is injured when it is used as an instrument of unfair competition "in the distribution of goods produced under substandard labor conditions." *Id.* at 115. This case extended the reach of the

Commerce Clause to local manufacturing operations—an intrastate activity—that this Court had previously determined was beyond the scope of congressional authority. *Id.* at 115-117. This Court explained the scope of that authority in these terms:

> The power of Congress over interstate commerce is not confined to the regulation of commerce among the states. It extends to those activities intrastate which so affect interstate commerce or the exercise of the power of Congress over it as to make the regulation of them appropriate means to the attainment of a legitimate end, the exercise of the granted power of Congress to regulate interstate commerce.

Id. at 118.

Once again, this Court's inquiry was directed at both the significance of the regulated activities' effect on interstate commerce and the legitimacy of the end, or purpose, of the regulation (i.e., whether Congress was exercising control over interstate commerce).

In a further extension of the "substantial effects" category of Commerce Clause enactments, this Court upheld the economic regulation of local wheat production in *Wickard v. Filburn* under the Agricultural Adjustment Act of 1938.

Among other things, that Act involved a national regulatory scheme to control the price of wheat by regulating the volume of wheat on the market. "Acreage limitations were the Act's primary tool for controlling the supply of federally subsidized crops." Jim Chen, *Filburn's Legacy*, 52 Emory L.J. 1719, 1734 (Fall 2003). Before the 1941 planting season, it was clear that the low prices for wheat were the result of excessive supply. *Id.* "Only stiffer penalties on excess production could

prevent already overflowing stocks from surpassing the all-time high, which had been reached in 1940." *Id.*

Under the Act, the Secretary of Agriculture was directed "to proclaim a national acreage allotment for each year's wheat crop . . . ." *Id.* at 1735. Because of a growing fear of a glut in the market and the associated price crash, allotments were set and penalties raised for excess crops during the 1941 growing season. *Id.* Roscoe Filburn was subject to this regulation.

Filburn was a lifelong farmer who raised dairy cattle and poultry. He also grew wheat which he sold, fed to his cattle and poultry, and used for household consumption. *Id.* at 1734. Additionally, Filburn ran a commercial business selling milk and eggs to about 75 customers a day from the cattle and poultry he fed with the wheat. *Id.* Filburn's allotment was 11.1 acres, but he planted 23 acres instead. The extra acreage yielded 239 bushels of wheat in excess of Filburn's allotment. Filburn was, therefore, fined for the excess, which he subsequently challenged in federal court.

On review, this Court found that home-grown wheat competes with wheat in interstate commerce either by entering the market or, if consumed by the grower, reducing the purchase of wheat in the market. *Wickard*, 317 U.S. at 128. And while the grower's "own contribution to the demand for wheat may be trivial by itself," this Court held that the aggregate economic effect of "others similarly situated, is far from trivial" and can be regulated. *Id.*

By amassing trivial effects of similar activity to find a "substantial effect" on interstate commerce, *Wickard* pushed the very limits of Congress' Commerce Clause authority. Never had this Court so liberally construed or so broadly applied the commerce power.

Together, *Jones & Laughlin Steel*, *Darby*, and *Wickard* ushered in a new era of expanding federal regulation of

intrastate activity that seemed to recognize no limit on congressional authority under the Commerce Clause. *See* Arthur B. Mark III, *United States v. Morrison, The Commerce Clause and the Substantial effects test: No Substantial Limit on Federal Power*, 34 Creighton L. Rev. 675 (April 2001) (arguing that aggregation under the substantial effects standard provides no meaningful stopping point to the reach of the commerce power).

Indeed, the lower courts have relied on these cases to justify federal regulation of intrastate, noncommercial activity, such as arson, robbery, and other crimes, without regard to the inherent limitations of the commerce power. However, in *Lopez* and *Morrison*, this Court declared it had gone far enough in broadening the scope of the Commerce Clause and drew a constitutional line at *Wickard* over which Congress may not pass.

Contrary to the prevailing view in the lower courts that federal jurisprudence required the proverbial rubber stamp on Congress' Commerce Clause enactments, this Court found in *Lopez* and *Morrison* that its Commerce Clause cases, including *Jones & Laughlin Steel*, *Darby*, and *Wickard*, established definite limits to the commerce power. From these limits, this Court built a simple framework for analyzing "substantial effects" and determining the constitutionality of certain Commerce Clause legislation, such as the CSA in this case.

A. Under *Lopez*, Intrastate Activity May Be Regulated for its Substantial Effects on Interstate Commerce Only If the Regulated Activity Is Economic in Nature

Alfonso Lopez, Jr., was indicted for violating the Gun-Free School Zones Act of 1990. *Lopez* at 551. That Act made it a federal offense "for any individual knowingly to possess a firearm . . . at a place that the individual knows, or has reasonable cause to believe, is a school zone." 18 U.S.C.

§ 922(q)(1)(A). The term school zone was defined as "in, or on the grounds of, a public, parochial or private school" or within a distance of 1,000 feet of such a school. 18 U.S.C. § 921(a)(25).

On March 10, 1992, Lopez, a 12th-grade student, arrived at school with a concealed .38 caliber handgun and five bullets. *Lopez*, 514 U.S. at 551. He was arrested and initially charged with firearm possession under state law, but the state law charges were dropped when federal officers charged Lopez with a federal crime under § 922(q) of the Gun Free School Zones Act. *Id.*

Lopez sought to dismiss the indictment as beyond the commerce power of Congress. *Id.* But the district court upheld the Act holding that § 922(q) "is a constitutional exercise of Congress' well-defined power to regulate activities in and affecting commerce." *Id.* at 551-552. On appeal, however, the Fifth Circuit reversed and held that "section 922(q), in the full reach of its terms, is invalid as beyond the power of Congress under the Commerce Clause." *Id.* at 552. This Court affirmed. *Id.*

Starting with first principles, this Court observed that the "Constitution creates a Federal Government of enumerated powers." *Id.* This principle was "adopted by the Framers to ensure protection of our fundamental liberties" by maintaining the balance of power between the States and the Federal Government so as to reduce the risk of abuse from either side. *Id.* As for the enumerated power, delegated to Congress, "'to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes,' Art. I, § 8, cl. 3", this Court emphasized the inherent limitations found in the very language of the clause. *Lopez*, 514 U.S. at 553.

When this Court first defined the commerce power in *Gibbons v. Ogden*, 22 U.S. 1 (1824), it recognized that

> [c]omprehensive as the word "among" is, it may very properly be restricted to that commerce which concerns more States than one . . . . The enumeration presupposes something not enumerated; and that something, if we regard the language, or the subject of the sentence, must be the exclusively internal commerce of a State.

Lopez, 514 U.S. at 553 (citing *Gibbons*). Another inherent limitation to the commerce power, recognized by this Court, was that the commerce power is the power to regulate or to "prescribe the rule by which commerce [itself] is governed." *Id.*

In *Lopez*, this Court credited *Jones & Laughlin Steel*, *Darby*, and *Wickard* for creating an era of constitutional jurisprudence that greatly increased the commerce power of Congress beyond the limits previously defined by this Court. *Id.* at 556. But, as this Court pointed out, even these expansive precedents affirmed that the commerce power is "subject to outer limits." *Id.* at 557.

What are those limits? This Court cited the admonition of *Jones & Laughlin Steel* that the commerce power is constrained by our dual system of federal and state government and may not be stretched to encompass "indirect and remote" effects on interstate commerce so as to extinguish "the distinction between what is national and what is local and create a completely centralized government." *Id.* (citing *Jones & Laughlin Steel*).

This Court also took pains to characterize *Wickard* as this Court's "most far reaching example of Commerce Clause authority over intrastate activity." *Id.* at 560. But, this Court emphasized that at least that case involved some *economic activity* and that the Agricultural Adjustment Act upheld by this Court was directed at regulating competition in commerce which was directly affected by home-grown wheat. *Id.* This Court concluded that it had always observed the constitutional

structure, even in those cases where the congressional enactment was upheld based on "substantial effects," and that this Court's inquiry in such cases was "to decide whether a rational basis existed for concluding that a regulated activity sufficiently affected interstate commerce." *Id.*

After laying the foundation of a limited commerce power, this Court had no difficulty finding that the Gun-Free School Zones Act had exceeded Congress' Commerce Clause authority and was constitutionally invalid. The framework this Court followed in reaching this conclusion is simple and straight forward.

This Court readily determined that *Lopez* was a "substantial effects" case. For that determination, this Court looked at the object of § 922(q) and observed that it did not purport to regulate the use of channels of interstate commerce or prohibit the interstate transportation of a commodity through the channels of commerce. *Id.* at 559. Likewise, because the statutory provision prohibited mere possession of a gun in a school zone, it could not be justified as a regulation to protect an instrumentality of interstate commerce or a thing in interstate commerce. *Id.* at 561. If § 922(q) was to be upheld, it would have to be under the third category of Commerce Clause enactments—"as a regulation of an activity that substantially affects interstate commerce." *Id.* at 559

First, this Court looked at the text of the statute and found that, unlike the act in *Wickard*, § 922(q) by its own terms had "nothing to do with 'commerce' or any sort of economic enterprise, however broadly one might define those terms." *Id.* 561. This obvious conclusion was compelled by the express language of the Act which made the mere possession of a firearm in a school zone a crime.

This Court also found that the regulated act, the possession of a gun, was "not an essential part of a larger regulation of economic activity, in which the regulatory scheme could be

undercut unless the intrastate activity were regulated." *Lopez* at 561. In fact, the Act was a criminal statute that did not involve a commercial or economic regulatory scheme at all. *Id.* Section 922(q) could not be sustained, therefore, under this Court's cases, like *Wickard*, that allowed congressional regulation of activities "that arise out of or are connected with a commercial transaction, which viewed in the aggregate, substantially affects interstate commerce." *Id.* Interestingly, this Court came to this conclusion even though the prohibited activity, possession of a gun, involved a commercial item.

After rejecting the aggregation approach to sustaining the regulation of an intrastate activity that is not economic in nature, this Court sought next to determine whether § 922(q) contained a "jurisdictional element" that would ensure on a case-by-case basis that the possession of a firearm substantially affects interstate commerce. *Id.* For that determination, this Court turned again to the language of the Act and found that it did not provide an express requirement that would "limit its reach to a discrete set of firearm possessions that additionally have an explicit connection with or effect on interstate commerce." *Id.* at 562. Because no substantial effect was "visible to the naked eye," in the text of the Act itself, this Court also looked to the legislative history to locate any express congressional findings that demonstrated Congress' belief that the possession of a gun in a school zone substantially affected interstate commerce. *Id.* at 562-563. But this Court found none.

Nevertheless, the government argued that Congress could rationally have concluded that § 922(q) did substantially affect interstate commerce because possession of a gun in a school zone may result in violent crime and violent crime interferes with the national economy in two respects: (1) violent crime increases the cost of insurance throughout the nation and (2) violent crime deters people from traveling to unsafe areas. *Id.* at 563-564. The government also argued that guns in school

undermine the learning environment, producing less productive citizens, which hurts the national economy. *Id.* at 564. To underscore the limitations on the commerce power, this Court addressed the implications of those arguments.

The government acknowledged under its "costs of crime" argument that Congress could regulate any activity that might lead to violent crime no matter how remote the connection to interstate commerce. *Id.* Likewise, this Court found that under the government's "national productivity" argument, Congress could regulate anything related to individual economic productivity. *Id.* If these arguments were accepted, this Court concluded it would be "hard pressed" to find any individual activity that Congress could not regulate under the commerce power. *Id.* "Depending on the level of generality," this Court observed, "any activity can be looked upon as commercial." *Id.* at 565.

This was the fallacy in the government's arguments; they provided no logical stopping point to congressional authority and converted the commerce power into a general police power like that enjoyed by the states. *Id.* at 567. Although some of this Court's earlier cases leaned in that direction and suggested a possible expansion of the commerce power, this Court set aside § 922(q) as an invalid Commerce Clause enactment and declined in *Lopez* to go any further. *Id.* "To do so," this Court stated, "would require us to conclude that the Constitution's enumeration of powers does not presuppose something not enumerated . . . and that there never will be a distinction between what is truly national and what is truly local." *Id.* at 567-568 (citing *Gibbons* and *Jones & Laughlin Steel*).

B. *Morrison* Affirmed That the "Substantial Effects" Standard Applies to Intrastate Activity Only if the Activity Is Economic in Nature

Morrison is instructive because of what it says about this Court's decision in *Lopez*. In the fall of 1994, Christy

Brzonkala enrolled at Virginia Polytechnic Institute. *Morrison*, 529 U.S. at 602. Shortly after meeting fellow students Antonio Morrison and James Crawford, Brzonkala alleged they assaulted and repeatedly raped her. *Id.* Brzonkala filed a complaint against the students under the school's Sexual Assault Policy. *Id.* at 603. After a hearing, the school's Judicial Committee found Morrison guilty of sexual assault and suspended him for two semesters. *Id.* Morrison's punishment was set aside, however, on administrative appeal. *Id.* Crawford was not punished due to lack of evidence. *Id.*

Brzonkala then filed a suit in federal court against Morrison and Crawford under § 13981 of the Violence Against Women Act of 1994. That Act provided a federal civil remedy for victims of gender-motivated violence and stated that "persons within the United States shall have the right to be free from crimes of violence motivated by gender." 42 U.S.C. § 13981(b). The Act defined a crime of violence motivated by "gender" as "a crime of violence committed because of gender or on the basis of gender, and due, at least in part, to an animus based on the victim's gender." 42 U.S.C. § 13981(d)(1). The district court dismissed the suit because it determined that § 13981 was an invalid Commerce Clause enactment. The en banc court of appeals and this Court both affirmed.

Returning to "first principles," this Court reaffirmed that all laws passed by Congress must find authority in the Constitution and that the powers of Congress are limited. *Morrison*, 529 U.S. at 607. As this Court emphasized, "even under our modern, expansive interpretation of the Commerce Clause, Congress' regulatory authority is not without effective bounds." *Id.* at 608.

Because § 13981 focused "on gender-motivated violence wherever it occurs" and was not directed at the instrumentalities of interstate commerce or interstate markets, or even things or persons in interstate commerce, the majority determined that the

Act fell within the third category of Commerce Clause enactments and could only be sustained as a regulation of activity that substantially affects interstate commerce. *Id.* at 609. To conduct its analysis, this Court concluded that *Lopez* provided the appropriate framework. *Id.*

According to this Court, four factors contributed to the decision in *Lopez*. The first factor was that the statute, by its terms, had nothing to do with commerce or an economic enterprise; that is, the Act did not purport to regulate an economic activity. *Id.* at 610. The second factor was that the Act contained "no express jurisdictional element which might limit its reach to a discrete set of firearm possessions that additionally have an explicit connection with or effect on interstate commerce." *Id.* at 611. This factor was important to establish that the Act was in "pursuance of Congress' regulation of interstate commerce." *Id.* The third factor was that neither the statute "nor its legislative history contain[ed] express congressional findings regarding the effects upon interstate commerce" of the regulated activity. *Id.* at 612. And, the fourth factor was that the connection between the regulated activity and a substantial effect on interstate commerce was remote. *Id.*

With this framework underlying this Court's Commerce Clause analysis, resolution of the *Morrison* case was clear. *Id.* at 613. First, this Court held, as it must, that the statute, by its terms, had nothing to do with commerce: "gender-motivated crimes of violence are not, in any sense of the phrase, economic activity." *Id.* As a result, gender-motivated crimes are not the type of activity that, through repetition elsewhere, would substantially affect interstate commerce. *Id.* at 610-611. Not even *Wickard*'s aggregation principle was availing. *Id.* at 611 n.4.

This was critical to the outcome of the case. As the majority observed, the noneconomic, criminal nature of the

prohibited activity in *Lopez* was central to its decision in that case. *Id.* at 610. But this Court did not stop there. To further illustrate the importance of this factor, this Court stated, as a matter of historical fact, that it had upheld federal regulation of intrastate activity based on its "substantial effects" on interstate commerce *only* when the regulated activity was economic in nature. *Id.* at 611, 613.

Next, this Court held that the Violence Against Women Act did not contain an express "jurisdictional element" establishing that Congress was attempting to regulate interstate commerce. *Id.* at 613. Rather than limit its reach to a discrete set of gender-motivated violent crimes that had an explicit connection with or effect on interstate commerce, § 13981 was drawn too broadly and included purely intrastate violent crime. *Id.* The language of the Act did not support the conclusion, therefore, that § 13981 was adequately tied to interstate commerce. *Id.*

Unlike the situation in *Lopez*, however, this Court did find that the Violence Against Women Act was supported by congressional findings that gender-motivated violence affects interstate commerce. *Id.* at 614. Among others, those effects included deterring victims from traveling interstate or engaging in interstate business. *Id.* at 615. Diminishing national productivity, increased medical costs, and a decrease in the supply and demand of interstate goods were also cited. *Id.* But this Court did not believe that these findings were sufficient to uphold the Act under the Commerce Clause. *Id.* "Simply because Congress may conclude that a particular activity substantially affects interstate commerce does not make it so." *Id.* at 614. That determination, the majority held, is for the courts to decide. *Id.*

Finally, because Congress followed the but-for causal chain from the original violent act to every remote effect upon interstate commerce, this Court decided that Congress' findings

were faulty and relied on a "method of reasoning" that obliterates the distinction between what is national and what is local and which this Court had already rejected in *Lopez*. *Id.* at 615. This Court was unwilling to allow Congress to regulate noneconomic activity, such as gender-motivated acts of violence, based only on that activity's attenuated effects on interstate commerce. *Id.* at 617. Therefore, this Court held that Congress did not have authority under the Commerce Clause to enact § 13981 of the Violence Against Women Act. *Id.* at 619.

II

"FIRST PRINCIPLES" RECOGNIZE THE INHERENT LIMITS OF THE COMMERCE CLAUSE AND DICTATE THAT COMMERCE CLAUSE ENACTMENTS PURSUE A LEGITIMATE COMMERCE CLAUSE OBJECTIVE—THE GOVERNANCE OF INTERSTATE COMMERCE

This Court's repeated reference to "first principles" seems to get lost in the academic debate over this Court's Commerce Clause jurisprudence. However, in *Lopez* and *Morrison*, this Court's understanding of "first principles" determined the outcome of those cases. As explained in *Lopez*, and reiterated in *Morrison*, this Court understood "first principles" to mean that the Constitution established a federal government of enumerated powers which are few and defined in contrast to the powers of the States which are numerous and indefinite. *Lopez*, 514 U.S. at 552.

This limitation on federal authority was necessary, this Court stressed, to ensure our fundamental liberties and protect the nation against unfettered federal power and a "completely centralized government." *Id.* at 552-555. Consequently, while some cases had broadly construed the power delegated to Congress to regulate commerce, this Court noted in *Lopez* that it had never abandoned "first principles" and its cases had set

distinct limits on Congress' exercise of the commerce power. *Id.* at 556-557.

This conclusion was not just an observation. It was a statement of substantive law. This Court took pains to trace the development of its Commerce Clause cases from *Gibbons v. Ogden*, in which this Court initially defined the nature of the commerce power, to *Jones & Laughlin Steel*, *Darby*, and finally *Wickard*. *Id.* at 553-556. Nearly half of the majority opinion in *Lopez* is devoted to extracting from these cases the fundamental concept that the Commerce Clause has distinct limits.

In its Commerce Clause cases, this Court variously, but consistently, defined those limits in terms of the legitimate ends for which the commerce power could be employed. Starting with *Gibbons*, this Court affirmed that the commerce power was the power to regulate commerce. *Id.* at 553. In other words, the *Gibbons* Court recognized that Congress has authority to regulate commerce itself. This Court saw that as an inherent limitation on the commerce power. *Id.*

In *Gibbons*, this Court observed that the constitutional grant of authority to regulate interstate commerce presupposes that Congress cannot regulate that which is not interstate commerce, such as purely intrastate commerce. *Id.* (citing *Gibbons*). And while this Court seemed to lean away from this restrictive view of the commerce power in its earlier cases, this Court did not lose sight of the principle that the legitimate end of the commerce power is the regulation of interstate commerce.

Even when this Court was stretching the bounds of the Commerce Clause to encompass some types of intrastate activity, the touchstone of this Court's "substantial effects" cases was whether the statute governed interstate commerce.

In *Jones & Laughlin Steel*, this Court held that Congress may regulate intrastate activities the control of which is

"essential or appropriate to protect [interstate] commerce from burdens and obstructions." *Jones & Laughlin Steel*, 301 U.S. at 37. Likewise, in *Darby*, this Court held that Congress can regulate intrastate activities for the "attainment of a legitimate end, the exercise of the granted power of Congress to regulate interstate commerce." *Darby*, 312 U.S. at 118. And, in *United States v. Wrightwood Dairy Co.*, 315 U.S. 110 (1942), which was decided the same year as *Wickard*, this Court held that the power of Congress to regulate commerce "extends to those intrastate activities which in a substantial way interfere with or obstruct the exercise of the granted power." *Id.* at 119.

The unifying theme in these cases is that the power to regulate interstate commerce is limited to the power to enact "all appropriate legislation" for "its protection and advancement." *Jones & Laughlin Steel*, 301 U.S. at 37. This fundamental principle greatly simplifies Commerce Clause analysis under the "substantial effects" category and is the key to understanding *Lopez* and *Morrison*.

In *Lopez* this Court opened with its holding:

> The Act neither regulates a commercial activity nor contains a requirement that the possession [of a gun] be connected in any way to interstate commerce. We hold that the Act exceeds the authority of Congress "to regulate Commerce . . . among the several States . . . ."

Lopez, 514 U.S. at 551.

That statement of this Court's ultimate holding in the *Lopez* case is a succinct pronouncement of the constitutional standard for determining if a statute "substantially affects" interstate commerce. A statute that, by its terms, does not regulate a commercial or economic activity and does not expressly require that the regulated activity have any connection with interstate commerce is clearly not enacted to protect or

advance interstate commerce. Such a statute cannot be said, therefore, to be in pursuance of a legitimate Commerce Clause end—the exercise of Congress' power to govern interstate commerce.

This conclusion follows from this Court's understanding of "first principles" which dictate meaningful limits to the commerce power to protect the federal-state balance. Accordingly, the first *Lopez* factor is directed at determining whether Congress chose to regulate an economic or commercial activity, whereas the other three *Lopez* factors are directed at determining whether Congress required the regulated activity to have a direct and concrete connection to interstate commerce.

> In short, the determinative test of the exercise of power by the Congress under the Commerce Clause is simply whether the activity sought to be regulated is "commerce which concerns more States than one" and has a real and substantial relation to the national interest.

Heart of Atlanta Motel, Inc., v. United States, 379 U.S. 241, 255 (1964).

III

THIS COURT NEEDS TO REINFORCE *LOPEZ* AND *MORRISON* WITH A CLEAR STATEMENT THAT CONGRESS CANNOT REGULATE INTRASTATE ACTIVITY UNDER THIS COURT'S "SUBSTANTIAL EFFECTS" STANDARD UNLESS THE ACTIVITY IS ECONOMIC IN NATURE

Although this Court delineated the scope of the Commerce Clause in *Lopez* and *Morrison,* federal regulation of local activities that have nothing to do with interstate commerce continues, even in the face of constitutional challenge. This type of regulation often is justified by the lower courts' putative application of the "substantial effects" standard. *See*, for

example, *United States v. McFarland*, 311 F.3d 376, 378-379 (5th Cir. 2002) (Federal conviction under the Hobbs Act for convenience store robberies in Fort Worth, Texas. Court found substantial effects on interstate commerce without evidence that the stores had any "facilities, property, employees, bank accounts, or activities" outside the city.); *Jones v. United States*, 529 U.S. 848 (Federal conviction for arson of an owner-occupied home. Lower court found substantial effects on interstate commerce based on fact that home received out of state natural gas and was covered by out of state mortgage and insurance policy. Reversed by this Court on statutory grounds.); *United States v. Deaton*, 332 F.3d 698 (4th Cir. 2003) (Violation of Clean Water Act for discharge without a permit. Court found that Congress could regulate trivial discharges to small intrastate, nonnavigable wetlands based on *Wickard* aggregation.); and, *GDF Realty Investments, Ltd. v. Norton*, 326 F.3d 622 (5th Cir. 2003) (Prohibition on the "taking" of isolated, noncommercial cave-dwelling insects under the Endangered Species Act upheld. Court found Congress may prohibit "takes" of noncommercial species because such regulation is a necessary part of a scheme to protect the nation's genetic heritage which substantially affects interstate commerce.) (Currently on petition for writ of certiorari in this Court, Case No. 3-1454.)

These and similar cases involve the regulation of intrastate, noncommercial activity that far exceeds the constitutional limits set in *Lopez* and *Morrison*. Indeed, they go beyond the expansive reading of the commerce power in *Wickard*: "Even *Wickard*, which is perhaps the most far reaching example of Commerce Clause authority over intrastate activity, involved economic activity . . . ." *Morrison*, 529 U.S. at 610.

This Court has never upheld federal regulation of intrastate activity, based upon that activity's substantial effects on interstate commerce, unless the activity was "some sort of

economic endeavor." *Morrison*, 529 U.S. at 611. The key in this case, then, as with other "substantial effects" cases, is whether the activity the federal government seeks to regulate is "some sort of economic endeavor" that also has a substantial effect on interstate commerce. Federal Commerce Clause regulation that goes beyond this limit, and encompasses intrastate, noncommercial activity, acknowledges no stopping point to federal power. Rather, it destroys all distinction between what is national and what is local in violation of this Court's precedents and constitutional constraints.

Clearly, *Lopez* and *Morrison* do not provide an effective guide to defining the reach of federal regulation under the Commerce Clause when applied to intrastate, noncommercial activity. Nor do these cases provide a stable bulwark for the protection of our fundamental liberties by maintaining the balance of power between the States and the Federal Government. *See Lopez*, 514 U.S. at 552. But if the commerce power is constrained by our dual system of government, and this Court is willing to stand on "first principles" as it said it did in *Lopez* and *Morrison*, then this Court should more clearly define the scope of the commerce power.

This case presents Commerce Clause issues like those discussed above and addressed in *Lopez* and *Morrison*. This case provides the Court an opportunity, therefore, to state unequivocally that Congress *cannot* regulate intrastate activity that is not economic in nature under the "substantial effects" category of Commerce Clause enactments.

However this Court decides this case, it should not adopt a mode of analysis that enlarges the federal commerce power or justifies the regulation of intrastate, noncommercial activity which this Court has never before sustained.

CONCLUSION

The purpose of the *Lopez* inquiry is to determine if Congress *intended* to regulate commerce and then to ascertain "whether a rational basis existed for concluding that a regulated activity sufficiently affected interstate commerce." *Lopez*, 514 U.S. at 557. A straightforward application of the "*Lopez* factors" would demonstrate that a federal statute that purports to regulate intrastate, noncommercial activities cannot be sustained under the Commerce Clause. This Court should make it clear that such a statute does not substantially affect interstate commerce.

DATED: August, 2004.

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In The
Supreme Court of the United States

JOHN D. ASHCROFT,
Attorney General, et al.,

Petitioners,

v.

ANGEL MCCLARY RAICH, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF *AMICUS CURIAE* OF REASON FOUNDATION IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Does the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, exceed Congress' power under the Commerce Clause as applied to the intrastate cultivation and possession of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use?

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INTEREST OF *AMICUS CURIAE*

Pursuant to Supreme Court Rule 37, Reason Foundation respectfully submits this brief *amicus curiae* in support of respondents on the merits.[1]

Amicus Curiae Reason Foundation is a national research and educational organization. Reason Foundation advances the ideas of individual liberty, free markets, and the rule of law. Reason Foundation uses journalism and public policy research to influence the frameworks and actions of journalists, policymakers, and opinion leaders.

The world leader in privatization, Reason Foundation is known for practical and innovative public policy ideas that emphasize competition, transparency, and accountability for results. Reason Foundation conducts research on the role of choice, local knowledge, and a dynamic market economy in human progress. Reason Foundation has participated as *Amicus Curiae* in significant cases involving individual rights and the rule of law, including *Gratz v. Bollinger*, 539 U.S. 244 (2003) and *Grutter v. Bollinger*, 539 U.S. 306 (2003).

Reason Foundation publishes *Reason* magazine, which has a circulation of 55,000. *Reason*, the magazine of Free Minds and Free Markets, covers politics, culture, and ideas.

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[1] Pursuant to Supreme Court Rule 37.6, *Amicus Curiae* affirms that no counsel for any party authored any part of this brief and no person or entity made a monetary contribution for the preparation or submission of this brief. Respondents have consented to the filing of this brief. The parties have provided written consent to the filing of this brief.

Reason Foundation is an Internal Revenue Code section 501(c)(3) nonprofit corporation incorporated in 1978 and funded by private, voluntary contributions.

SUMMARY OF ARGUMENT

Petitioners argue that the intrastate cultivation and possession of medical cannabis for personal, medicinal use by respondents, and those similarly situated, has a substantial affect on interstate commerce in marijuana.[2] Minimal empirical evidence is cited by petitioner to support their argument, and it appears unlikely that their conclusion can be substantiated. The Congressional findings referenced by petitioners do not take into account the affect of existing California law which continues to substantially prevent cannabis from being diverted into the commercial market.

Both California and federal law prohibit commerce in marijuana. California state law prohibits personal use and possession of marijuana, unless the person in possession can prove that they have an illness for which cannabis provides relief.

California does not enforce the federal prohibition on medicinal use of cannabis, which is its prerogative under our federal system. However, existing California law prohibits cannabis used for medicinal purposes from entering the commercial market. Cannabis cultivation is

[2] Federal law defines marijuana as "all parts of the plant Cannabis sativa L" with certain exceptions. 21 U.S.C. § 802(16). In this brief, the term "cannabis" refers to any part of the plant cannabis used for medical purposes.

limited to that which is necessary to satisfy the needs of cannabis patients. Patients can use cannabis for medicinal purposes only with the approval or recommendation of a physician. Physicians may only recommend or approve cannabis for illnesses for which cannabis provides relief. Physicians that falsely or fraudulently recommend or approve medical cannabis may have their licenses revoked. Physicians have been investigated and had their licenses suspended for such recommendations. The amount a qualified patient or their caregiver may possess is limited to that which is necessary to satisfy the patient's needs, and any patient or caregiver that puts cannabis into the stream of commerce remains subject to existing California and federal laws prohibiting sale. Therefore personal cultivation and possession of cannabis for medicinal purposes is unlikely to have a substantial affect on the interstate market for marijuana. Should circumstances change, the federal government no doubt would retain the right to prosecute such entry.

In the face of existing California law, there is scant evidence that federal law is necessary to prevent entry of cannabis into the illicit interstate market for recreational marijuana. Congress' findings in the Controlled Substances Act, 21 U.S.C. § 801 (1970) ("CSA") do not address the affect of tightly regulated, noncommercial possession of cannabis for medicinal purposes. Nor do they demonstrate that mere possession of cannabis for medicinal purposes has a substantial affect on interstate commerce – particularly where those in possession have a medical need for cannabis and their health and freedom would be jeopardized by letting their allotment enter the interstate market. Therefore, Congress' findings should be

disregarded as to the respondents and those similarly situated.

ARGUMENT

I. The Evolution of California's Medical Cannabis Law

As with federal law, California law generally prohibits the cultivation, possession, sale, and transportation of marijuana. Every person who transports, imports in-state, sells, furnishes, administers, or gives away any marijuana is guilty of a felony. Cal. Health & Safety Code § 11360(a). Possession and cultivation of marijuana are prohibited. *Id.* §§ 11357, 11358. Possession with intent to sell is a felony. *Id.* § 11359. Proof of possession with intent to sell may be circumstantial, and may consist of evidence as to the quantity of the narcotic, the manner of packaging, and the opinion of an expert that the marijuana was being held for sale. *People v. De La Torre*, 268 Cal. App. 2d 122, 126 (1968). It is a crime to maintain any place for the purpose of unlawfully selling, giving away, or using marijuana. *Id.* § 11366.

In 1996, California voters passed Proposition 215, which excepted qualified patients[3] and their designated caregivers from state prosecution for possession or cultivation of cannabis for the personal medicinal purposes of the Qualified Patient, upon recommendation or approval by a physician. *See* Cal. Health & Safety Code § 11362.5(d)-(e).

[3] Patients that are qualified to use cannabis medicinally under California law are referred to throughout this brief as "Qualified Patients."

This Proposition was enacted as the "Compassionate Use Act." *Id.* § 11362.5(a).

In 2004, Senate Bill 420 ("SB 420") (enacted as the "Medical Marijuana Program") was enacted into law. This act clarified the limits of cannabis which Qualified Patients could possess. *See id.* § 11362.77. Under SB 420, transportation, use of buildings and nonprofit sale of cannabis are not prohibited under California law. *Id.* § 11362.765(a).

The Medical Marijuana Program also provides for medical identification cards for Qualified Patients and their caregivers. These cards incorporate security measures similar to driver's licenses. *See id.* §§ 11362.72, 11362.735. The Program implemented a statewide registry of cardholders. *Id.* §§ 11362.715, 11362.72, 11362.74, 11362.745, 11362.76. Cannabis may not be used medically (or otherwise) at work, while operating a car or boat, within the vicinity of a school, or anywhere where anti-smoking laws apply. *Id.* §§ 11362.785, 11362.789.

The Medical Marijuana Program also provides for the creation of a state-sponsored research program to develop medical guidelines for the appropriate administration and use of cannabis. *See id.* § 11362.9(a)(2).

II. Petitioner Has Provided No Evidence that California Law Does Not Effectively Prevent Medical Cannabis Cultivation from Having a Substantial Affect on the Commercial Market for Recreational Marijuana

Proposition 215 exempted medical use of cannabis from state prosecution for cultivation and possession. In the eight years since the passage of Proposition 215,

California statutory and judicial law has clarified the scope of the medical exemption to state laws prohibiting cannabis. California has proscribed the conditions under which cannabis may be possessed. Patients must prove their medical need. Physicians cannot recommend cannabis unless it can be shown to treat illness. State mandated ceilings limit the amounts which patients and their caregivers may possess. Doctors that recommend cannabis have such recommendations scrutinized by the California Medical Board. Sale remains prohibited under California and federal law.

This legal regime effectively precludes cannabis from entering the interstate black market for recreational marijuana. Although individual instances of diversion of cannabis to illicit purposes undoubtedly occur, there is no evidence that cultivation of cannabis has had a "substantial affect" on the black market for recreational marijuana.

The Court need not take *Amicus* at their word. California has recently had record marijuana busts. The federal government's own studies reflect that abuse of the medical cannabis system has not resulted in routine diversion of cannabis for recreational or commercial purposes. *Tellingly, the federal government has not provided evidence that medical cannabis has had any impact on the commercial market for marijuana, let alone a substantial one.* Whether particular operations affect interstate commerce sufficiently to come under the constitutional power of Congress to regulate them is ultimately a judicial rather than a legislative question. *United States v. Morrison*, 529 U.S. 598, 614 (2000). The existing California regulatory framework is a key factor in any determination of whether intrastate cultivation and possession

has a substantial affect on the illicit, interstate market for marijuana.

Amicus does not argue that a comprehensive regime of state law regulation can divest Congress of its authority to regulate interstate commerce. However, it is now a firmly rooted constitutional principle that unless regulation concerns the channels or instrumentalities of commerce, an activity must have a "substantial affect" on interstate commerce in order to subject it to Congressional regulation under the Commerce Clause. *United States v. Lopez*, 514 U.S. 549, 558 (1995), *Morrison*, 529 U.S. at 609. Speaking purely as a descriptive matter, the State of California has adopted a system of regulation that meaningfully prevents medical cannabis from entering the commercial market for marijuana.

A. Patient and Caregiver Access Is Limited by Medical Approval

California has established a comprehensive system of controls that effectively keeps cannabis from entering the black market for recreational use. Doctors, Qualifying Patients, and the patients' caregivers are all regulated in an effort to prevent use of cannabis for anything other than medicinal purposes. Further, sick patients remain subject to state and federal criminal prosecution should their cannabis enter the recreational market.

Under California law, a Qualified Patient may use cannabis only for medicinal purposes upon a physician's approval or recommendation. Cal. Health & Safety Code § 11362.5(d). Before a patient is qualified, they must have cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or another illness for which cannabis

provides relief. *Id.* § 11362.5(b)(1)(A). A physician's approval or recommendation must be obtained before use occurs. California courts do not allow a physician's recommendation or approval to be made after use, unless a defendant can show that he used cannabis under "exigent circumstances." *People v. Rigo*, 69 Cal. App. 4th 409, 412-13 (1999) (finding no exigent circumstances).[4]

The requirement that patients have a demonstrated need for treatment acts as a means to monitor physicians as well as patients. The Medical Board of California has issued guidelines which provide that cannabis recommendations should be based on the results of clinical trials, if available, medical literature and reports, or on experience of that physician or other physicians, or on credible patient reports. In all cases, the physician must determine that the risk/benefit ratio of medical cannabis is as good, or better, than other medications that could be used for that individual patient. (Medical Board of California, "California Physicians and Medical Marijuana" (last visited October 12, 2004) <http://www.medbd.ca.gov/Guidelines_Marijuana.htm>). Physicians that recommend cannabis without a valid basis are sanctione by the Medical Board. *People v. Spark*, 121 Cal. App. 4th 259, 263 (2004) (Testifying physician admitted that he was no longer licensed to practice medicine at the time of trial. His license had been suspended for giving medical cannabis recommendations to four

[4] There are no reported cases in which "exigent circumstances" allowed post-use recommendation or approval under the Compassionate Use Act. Further, Lexis and Westlaw searches fail to reveal any nonreported cases in which exigent circumstances allowed post-use recommendation or approval.

undercover police officers). *See also Bearman v. Superior Court*, 117 Cal. App. 4th 463, 468-69 (2004) (medical cannabis patient's records can be subpoenaed in investigation by state medical board where good cause is shown). Therefore, the possibility of losing their medical license operates as a strong disincentive for physicians to fraudulently recommend cannabis for nonmedicinal purposes.

Someone cannot be the primary caregiver without being designated by a Qualified Patient. Cal. Health & Safety Code § 11362.5(d). In order to be a caregiver, a person must consistently assume responsibility for the housing, health, or safety of the Qualified Patient. *Id. See People v. Peron*, 59 Cal. App. 4th 1383, 1395 (1997). A person cannot functionally be a "primary caregiver" to a large number of people, they must have an ongoing personal relationship with the Qualified Patient. *See, Peron* at 1395-98.

Under California law, sick people can obtain medical cannabis only pursuant to a physician's recommendation. Caregivers must prove that their patient is qualified and that they have an ongoing relationship of care for that patient. The physician must provide a *bona fide* recommendation or face possible suspension of their license and criminal prosecution. Patients and their caregivers face criminal liability if they misappropriate medical cannabis for illicit purposes. Under these conditions, it is unlikely that the status of a physician, patient or caregiver would readily provide sufficient cover for an opportunistic participant in the commercial market.

B. Law Enforcement Retains Meaningful Constraints on Medical Cannabis Users Which Restrict Entry into the Illicit Market

Throughout California's experience with medical cannabis, law enforcement has consistently kept medical cannabis distinct from the illicit market for recreational use of marijuana. Marijuana does remain the same substance no matter whether it is used for medicinal or recreational purposes. However, from an enforcement perspective the purpose for which marijuana is used serves as a useful means of preventing it from entering the illicit market and having a substantial affect on interstate commerce.

Persons in possession of cannabis cannot retain possession unless such person verifies that the purpose of possession is for medicinal use. The Compassionate Use Act does not purport to provide medical cannabis patients with a right to possess cannabis. Rather, when a patient is arrested for possession of medical cannabis, the patient can seek to prove that the use is medicinal as an affirmative defense at trial. *People v. Trippet*, 56 Cal. App. 4th 1532, 1546 (1997), *People v. Mower*, 28 Cal. 4th 457, 469 (2002). Thus, where law enforcement officers or agencies believe that medical cannabis is being diverted for recreational purposes, they may seize the same, thereby preventing its entry into the market.

The California legislature recently authorized the creation of a statewide registry for state medical cannabis identification cards. Where a Qualified Patient or their caregiver in possession of statutorily limited amounts of cannabis presents this card to a state law enforcement officer, the patient or caregiver can avoid arrest, unless there is reasonable cause to believe that the information

contained in the card is false or falsified, that the card has been obtained by means of fraud, or the person is otherwise in violation of the law. Cal. Health & Safety Code § 11362.71(e). The identification cards for Qualified Patients will be readily distinguishable from the identification cards for caregivers. *Id.* § 11362.71(d)(3).

Though not yet implemented, the system will greatly increase law enforcement's ability to isolate and apprehend abusers of the medical cannabis exception. The registry will enable state and local law enforcement to verify identification card validity through a 24-hour database accessible through a 1-800 telephone number. *See id.* § 11362.71(a)(2). The database will be compiled from the counties' health departments, which first obtain the data by verifying individual patients' applications for identification cards. *See id.* § 11362(b).

To obtain an identification card, a patient must provide copies of medical records, created by the patient's attending physician. The application must reflect that the patient has a serious medical condition for which the physician deemed cannabis "appropriate." The attending physician must be identified by name, office address, office telephone number, and California medical license number; proof of residency within the issuing county; and a "government-issued photo identification card." *See id.* §§ 11362.7(i), 11362.715(a). The name and duties of their primary caregiver must also be provided. *Id.* § 11362.715(a)(4). Before it may issue an identification card, a county health department must verify that all information in the application is accurate. Also, it must verify that the attending physician has a license to practice in good standing. The county must contact the physician to verify the legitimacy of the medical records

submitted in the application. *Id.* § 11362.72(a)(1)-(a)(3). If the county issues an identification card, it must within 24 hours electronically transmit the identification card holder's information to the state department of health services. *Id.* § 11362.72(b).

The identification cards have the security provisions typically found in a government-issued identification card. Each card has a unique user identification number, the name and telephone number of the county health department, and the toll-free telephone number that State and local law enforcement officers can call at any time to obtain "immediate access" cardholder information. Each card must carry a photo identification of the patient or caregiver. *Id.* § 11362.735. All cards have an expiration date. Identification cards are valid for one year only, and the county health department must verify all of a patient's new information before it can renew the patient's Identification card. *Id.* § 11362.745(a). The county also may verify any other information that has not changed. *Id.* § 11362.745(b).

The person who possesses an identification card shall notify the county of any change in the Qualified Patient's attending physician or designated primary caregiver. *Id.* § 11362.76(a)(1). They must also annually submit written documentation of the person's serious health condition and the name and duties of the primary caregiver for the forthcoming year. *Id.* § 11362.76(a)(2). Failure to provide this information will result in expiration of the identification card. *Id.* § 11362.76(b).

California law provides strict prohibitions on attempts to fraudulently obtain or manipulate identification cards. Under the California Health and Safety Code, fine and

imprisonment can result for anyone who fraudulently represents a medical condition or fraudulently provides any material misinformation to a physician, county health department or the county's designee, or state or local law enforcement, for the purpose of falsely obtaining an identification card. *Id.* § 11362.81(a), (b)(1). The same punishment will be imposed on anyone who steals or fraudulently uses an identification card (*id.* § 11362.81(b)(2)) or who counterfeits, tampers with, or fraudulently produces an identification card (*id.* § 11362.81(b)(3)). Should a person engage in any of these activities, they may be precluded from attempting to obtain an identification card for six months. *Id.* § 11362.81(c). In addition, the Attorney General is charged with developing appropriate guidelines to ensure the security and nondiversion of cannabis grown for medicinal use by Qualified Patients. *Id.* § 11362.81.

Some California counties have already met with success in using identification cards to efficiently ascertain whether a person in possession of marijuana is a Qualified Patient. One county found that law enforcement resources are effectively conserved by readily drawing the distinction between Qualified Patients and those in possession for recreational purposes. (Mendocino County Sheriff's Office, *Medical Marijuana: Implementing Proposition 215*, <http://www.co.mendocino.ca.us/sheriff/Prop215.htm.>) Once the statewide registry is in place, California can expect even greater efficiency from law enforcement in separating Qualified Patients from fraudulent abusers of the system.

A study performed by the federal government suggests that federal law enforcement officers have not had their enforcement efforts impeded by diversion of medical marijuana, either. During review of federal law enforcement officers in a 2002 United States General Accounting

Office ("GAO") study, none of the federal officials the GAO interviewed provided information to support a statement that abuse of medical marijuana laws was routinely occurring in California. General Accounting Office, *Marijuana: Early Experiences with California's Laws that Allow Use for Medical Purposes* 37 (Nov. 2002). Were federal law enforcement efforts impeded by diversion, one might expect that the federal approach to enforcement would have changed in the eight years since Proposition 215 passed. However, federal law enforcement efforts have not substantially changed since California law enforcement ceased to prohibit medical marijuana. *Id.* at 32 (finding that introduction of medical cannabis laws had little impact on law enforcement officers operations and that the federal process of using case-by-case review of potential marijuana prosecutions has not changed as a consequence of state marijuana laws).

C. Patient and Caregiver Possession Restrictions Limit the Amount of Medical Cannabis Which Might Otherwise "Substantially Affect" the Interstate Market

Since California authorities ceased to prohibit cannabis for medical purposes, the state has limited the amount of cannabis Qualified Patients can possess to what is necessary for their treatment. Soon after Proposition 215 passed, a California Court of Appeal held that the quantity possessed by the patient or the primary caregiver, and the form and manner in which it was possessed, was limited to what was reasonably related to the patient's current medical needs. *Trippet* at 56 Cal. App. 4th 1549. This determination would be made by a judge or jury, as appropriate, but a significant piece of evidence in making this

determination would regularly be the recommending or approving physician's opinion regarding the frequency and amount of the dosage the patient needs. *Id.* at 1549.

The California legislature subsequently added greater clarity to the issue of amount. Upon passage of SB 420, a Qualified Patient or primary caregiver is entitled to possess no more than eight ounces of dried cannabis per Qualified Patient, and (to assure future supply), the patient or his or her caregiver may maintain no more than six mature or 12 immature plants per Qualified Patient. Cal. Health & Safety Code § 11362.77(a). By comparison, the federal government's "Compassionate Use Program," which provides cannabis to a handful of patients pursuant to an out-phased research program, has provided its patients with up to eleven cured ounces of cannabis every three weeks.[5]

A patient may possess no more than the statutory limits at any time, unless an exception applies. The Qualified Patient or caregiver can possess more than this amount only upon recommendation by a physician or upon countywide approval for greater limits. Further, the California Attorney General may, after public comment, recommend greater limits based on currently available scientific research.[6]

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[5] *See, e.g.*, Letter from Irvin Rosenfeld, federal medical cannabis patient, to whom it may concern (July 1, 1996) (on file with Reason Foundation) (11 ounces every three weeks); Letter from Barbara Douglas, federal medical cannabis patient, to whom it may concern (July 1, 1996) (on file with Reason Foundation) (nine ounces per month).

[6] If the patient needs more than the amount allowed under Cal. Health and Safety Code § 11362.77(a), then they must receive a doctor's

(Continued on following page)

Such restrictions assure that patients only receive the amount of cannabis they need to treat their ailments. Petitioners argue in their Brief that Qualified Patients can be expected to commonly divert cannabis they use as medicine to the illicit market, stating "Local users may ultimately sell or divert the drug to others . . . " (Brief at 25). However, this does not comport with self-interest of Qualified Patients or those persons such patients have chosen as their caregivers. Qualified Patients cannot be expected to routinely divert their medication in expectation of compensation. If they do, they will suffer their illness for lack of proper treatment.

Moreover, irrespective of the outcome of this case, California and federal law will both continue to prohibit sale of marijuana for recreational purposes. The Qualified Patients or caregivers will face the same state and federal criminal penalties should they put medical cannabis in the recreational market. Whether they possess a state-issued identification card or not, the accused will have to prove as an affirmative defense that the medical cannabis defense applies. *People v. Konow*, 32 Cal. 4th 995, 1003 (2004). (For-profit sale of marijuana remains prohibited under state law), *Mower*, 28 Cal. 4th at 469 (Compassionate Use Act does not provide a "complete immunity"

recommendation for the same. *Id.* § 11362.77(b). Also, in order to allow for geographical variances in production capacity, SB 420 provides that cities and counties may promulgate their own regulations allowing patients or qualified caregivers to exceed the state limits set forth in section 11362.77(c). The California Attorney General may also recommend modifications to the Legislature by December, 2005. Cal. Health & Safety Code § 11362.77(e).

whereby claimed patient can compel further investigation merely by claiming that he is a Qualified Patient.)[7]

Were a cannabis patient tempted to sell "excess" medical cannabis on the recreational market, they would encounter existing legal prohibitions under California and federal law.[8] Qualified Patients face the same criminal prohibitions as any other Californian should they exceed the amounts they may lawfully possess or transfer cannabis to a person other than a patient or caregiver. Cal. Health & Safety Code §§ 11362.77(a), 11357, 11359. Of course, once marijuana entered the stream of interstate commerce, patients or their caregivers would also be subject to prosecution under federal law. The same holds true for caregivers that possess or transfer cannabis to persons other than patients or caregivers. *Id.* These prohibitions make it doubtful that possession or cultivation of cannabis for medicinal purposes will have a substantial affect on interstate commerce for marijuana.

The foregoing legal structure does not provide a mere theoretical prohibition regarding commercial demand for medical marijuana. Rather, the theory behind Proposition 215 has been borne out in practice. California state law

[7] As noted above, persons who fraudulently attempt to or use, seek or tamper with identification cards may also be precluded from applying for the same. Cal. Health & Safety Code § 11362.81(c).

[8] Although California authorities will not assist federal authorities in preventing Qualified Patients from using marijuana, California law does not purport or threaten to supersede federal authority. For instance, if a small amount of marijuana were seized en route from Mexico or Las Vegas to San Diego, and the person in possession claimed a defense under California's Compassionate Use Law, there would be no question that interstate commerce occurred. California's law would neither purport to nor actually provide a defense to such person.

enforcement has an established track record of policing sales of illicit marijuana. In fact, the California Attorney General recently announced record-breaking seizures of "large-scale illegal marijuana grows." Office of the Attorney General, *Campaign Against Marijuana Planting Achieves Milestone for 2004 Eradication Season* (last visited October 12, 2004), *available at* http://ag.ca.gov/newsalerts/2004/04-103.htm. The Attorney General announced seizures in 2004 of a total of 471,128 plants worth an estimated $1.88 billion. This announcement was made on September 9, 2004 and therefore did not include plant seizures that will occur from September 10, 2004 through December 31, 2004. Yet the state had already surpassed its record of 466,054 plants seized in 2003 – which was also a record-breaking year. *Id.* Given this track record, it is unreasonable to assume that a trickle of diverted medical cannabis will affect the interstate illicit market.

III. The Congressional Findings in the Controlled Substances Act Should Not Be Given More than Minimal Weight in Determining Whether Respondents' Conduct Has a "Substantial Affect" on Interstate Commerce

Petitioners claim that the cultivation and possession of cannabis for medicinal purposes by respondents and those similarly situated has a substantial affect on the interstate market for marijuana. In support of this claim, they reference the Congressional findings in the CSA that provide, among other things:

> 1. After manufacture, many controlled substances are transported in interstate commerce (21 U.S.C. § 801(3)),

> 2. Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances (21 U.S.C. § 801(4)), and
>
> 3. Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate, and thus it is not feasible to distinguish between such substances in terms of controls. (21 U.S.C. § 801(5)).

(Pet'rs. Brief at pp. 4-5).

Based on these findings, Petitioners argue that allowing possession and cultivation by Qualified Patients and their caretakers within California necessarily will have a substantial impact on the interstate market for marijuana. They argue that from an enforcement perspective, all marijuana is the same, whether it is used recreationally or medicinally. Medical cannabis is fungible and can therefore meet illicit demand. Therefore, they argue that all use must be deemed commercial to allow for effective regulation. ("Moreover . . . respondents' manufacturing, distribution and possession activities themselves involved economic activity . . . to at least the same extent as Roscoe Filburn's home-grown production of wheat in *Wickard*. In both cases, the regulated individuals are producing a fungible commodity for which there is an established market and are doing so for their own use when they would otherwise be participants in a regulated market.") (Pet'rs. Brief at 37).

This analysis fails to take into account California and federal law which act as a barrier for medical cannabis to enter into the illicit market.

As set forth above, the class of people that can possess cannabis for medical purposes is limited. To obtain Qualified Patient status under California law, a person must have an illness for which cannabis provides relief, and receive the recommendation or approval of a physician. The physicians who evaluate the patient run the risk of losing their license should they provide a fraudulent recommendation. Caregivers must prove that they have been designated as primary caregivers by an identified Qualified Patient, and they must prove that they have consistently assumed responsibility for the housing, health or safety of that person. The "Qualified Patient" and "caregiver" classifications narrow who may possess or cultivate cannabis to an identifiable class of persons. Where the persons who can legally possess cannabis are ascertainable by reference to a medically verifiable standard, the chance of successful false claims of status is minimized. Therefore, possession for medicinal as opposed to recreational purposes is ascertainable from an enforcement perspective.

Just as certain amounts have always been deemed presumptive of an intent to sell, the limits on possession established by California law also act as an indicator of whether cannabis is used for medicinal or recreational purposes. Neither Qualified Patients nor their caretakers can possess an amount of cannabis in excess of that allowed under state law. The limits under California state law operate as a bright line separating a sick person or their caretaker from a drug dealer. The limits on possession therefore act as an additional guarantor that those who can prove Qualified Patient or caretaker status do not abuse such status and begin selling marijuana. Because the state limits indicate if someone is abusing their status,

the limits reinforce the difference between cannabis and recreational marijuana for enforcement purposes.

Petitioners further argue that Qualified Patients and their caregivers can be expected to divert cannabis to the illicit market in such frequency that it would result in a substantial affect on the interstate market. ("The 'home-grown' manufacturing, free distribution, and possession of controlled substances ... pose an appreciable risk of diversion to others (for instance, should their production yield exceed their purported needs or should additional funds be required to finance their drug production or other activities).") (Pet'rs. Brief, pp. 25-26). But this speculative inference from the Congressional findings about "swelling" of the interstate market for marijuana is wholly unsubstantiated.

California law limits the amount of cannabis Qualified Patients may possess. Qualified Patients would risk their health if they attempted to divert cannabis. With the amount of cannabis patients may possess limited to their needs, patients would choose remuneration over their own health should they divert their cannabis. While this may occur in some instances, it is not likely that it would occur with sufficient frequency to affect the interstate market. Further, even more severe risks to the patient's health can occur should they divert medical cannabis. They may be deprived of treatment while awaiting trial in an attempt to prove the affirmative defense of medicinal use.

Of course, California state law does not purport to change federal law prohibiting sale. Because illicit sales remain unlawful under state law, Qualified Patients and their caregivers also risk their liberty should they attempt to divert medical cannabis into the illicit market.

Moreover, respondents do not contend that they have a right to buy or sell marijuana. They and those similarly situated with them simply wish to cultivate it for personal, medicinal use.

Petitioners' cited Congressional findings simply do not substantiate the inferences they draw. Where only a distinct, identifiable class of persons can possess a limited amount of cannabis, and certain amounts indicate that possession is not for medicinal use, then cannabis is distinguishable from recreational marijuana for enforcement purposes. Where patients risk their health and freedom by diverting cannabis, they cannot in the absence of credible evidence lightly be presumed to frequently engage in that course of conduct.

The existence of Congressional findings is not by itself sufficient to sustain the constitutionality of Commerce Clause legislation. *United States v. Morrison*, 529 U.S. at 614. The judiciary ultimately determines whether particular operations affect interstate commerce sufficiently to come under the constitutional power of Congress to regulate them. *Morrison* at 614. Ultimately, it is the government which carries the burden of establishing that a party's conduct has an affect on interstate commerce. *United States v. Farmer*, 924 F.2d 647, 651 (7th Cir. 1991). (RICO case). The government has not met this burden.

Petitioners rely on Congressional findings which claim that cannabis use is indistinguishable from recreational use. California law suggests otherwise. In California, patients are identified using objective medical criterion that is evaluated by the California Medical Board. Possession of a suspicious amount by a nonpatient or caregiver serves as indicia that nonmedical use is occurring.

Similarly, Petitioners have not provided any evidence that respondents, or anyone similarly situated to them, have diverted their cannabis into commerce. They have not presented any evidence that diversion occurs in an amount sufficient to have a substantial affect on the interstate market. Instead, they offer the conclusory argument that such diversion would routinely occur. In light of the fact that patients have their health endangered and their liberty deprived, this argument should be viewed with skepticism.

The question of Congressional power under the Commerce Clause is ultimately one of degree. *Lopez* at 566-67. Much as with the possession of a gun by the defendant in *Lopez*, the respondents' possession of medical cannabis which was cultivated purely interstate does not implicate the Commerce Clause. There is no indication that the respondents here "recently moved in interstate commerce." *Id.* Nor is there "any requirement that [their possession] of [cannabis] have any concrete tie to interstate commerce." *Id.* Further, California's laws act as a powerful disincentive for those similarly situated to respondents to place their cannabis into the stream of interstate commerce. Of course, the federal government's prohibition of sale would remain undisturbed by this Court's Commerce Clause established jurisprudence.

CONCLUSION

Unless petitioners can show that respondents' actions had a substantial affect on interstate commerce, Congress may not constitutionally prohibit respondents' intrastate possession and cultivation of medical cannabis.

California's regulatory regime casts grave doubt on the Congressional findings cited by petitioners. The class of persons who may possess cannabis is limited by a medically ascertainable standard. Even once those persons meet this standard, they remain subject to criminal sanction under California and federal law. Should they put cannabis into interstate commerce, they will be subject to federal prosecution. State prosecution will follow should respondents or those similarly situated possess or cultivate an amount of marijuana not allowed under California law. Should cannabis patients be subjected to legal scrutiny, they will have to prove medicinal use as an affirmative defense.

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BRIEF

(9)

No. 03-1454

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In The
Supreme Court of the United States

JOHN D. ASHCROFT, Attorney General, et al.,

Petitioners,

v.

ANGEL McCLARY RAICH, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF U.S. REPRESENTATIVE MARK E. SOUDER; U.S. REPRESENTATIVE CASS BALLENGER; U.S. REPRESENTATIVE DAN BURTON; U.S. REPRESENTATIVE KATHERINE HARRIS; U.S. REPRESENTATIVE ERNEST J. ISTOOK, JR.; U.S. REPRESENTATIVE JACK KINGSTON; AND U.S. REPRESENTATIVE DOUG OSE, AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, exceeds Congress's power under the Commerce Clause as applied to the intrastate cultivation and possession of marijuana for purported personal "medicinal" use or to the distribution of marijuana without charge for such use.

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INTEREST OF AMICI AND SUMMARY OF ARGUMENT[1]

Amici are Members of the U.S. House of Representatives, each of whom has taken a strong interest in drug and narcotics policy. Representative Mark E. Souder is Co-Chair of the Speaker's Task Force For a Drug-Free America ("Speaker's Task Force"), and Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources (Government Reform Committee), which has oversight over all aspects of federal narcotics policy. Representative Cass Ballenger is a member of the Speaker's Task Force, and Chairman of the Subcommittee on the Western Hemisphere (International Relations Committee). Representative Dan Burton is a member of the Speaker's Task Force, and Chairman of the Subcommittee on Human Rights and Wellness. Representative Katherine Harris is a member of the Speaker's Task Force, and Vice Chair of the Subcommittee on the Western Hemisphere (International Relations Committee). Representative Ernest J. Istook, Jr., is a member of the Speaker's Task Force, and Chairman of the Subcommittee on Transportation and Treasury, and Independent Agencies (Committee on Appropriations), which has responsibility for the annual budget of the federal Office of National Drug Control Policy. Representative Jack Kingston is a member of the Speaker's Task Force, and Chairman of the Subcommittee on the Legislative Branch (Committee on

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[1] The parties have consented to the filing of this brief. Counsel for a party did not author this brief in whole or in part. No person or entity, other than the Amici Curiae, the Subcommittee on Criminal Justice, Drug Policy and Human Resources (Government Reform Committee), or their counsel, made a monetary contribution to the preparation and submission of this brief.

Appropriations). Representative Doug Ose is a member of the Speaker's Task Force, and Chairman of the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs (Government Reform Committee).

Drug abuse remains the nation's most important public health problem. Each year, over 20,000 people die as a direct consequence of drug abuse, while many thousands more end up in emergency rooms due to drug-related causes. *See* Centers for Disease Control, *Deaths: Preliminary Data for 2002*, National Vital Statistics Reports, at 18 (Feb. 11, 2004); Substance Abuse & Mental Health Servs. Admin., *Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995-2002* (July 2003). The annual economic costs of drug abuse to the nation as a whole have been estimated at $143.2 billion, including $12.9 billion in health care costs (such as emergency medical care, and drug abuse treatment) and $98.5 billion in lost productivity. Executive Office of the President, Office of National Drug Control Policy, *The Economic Costs of Drug Abuse in the United States, 1992-1998*, at 2, 4-6 (2001).

Drug abuse is facilitated by an illegal but nationwide and flourishing market for illicit drugs. Congress and the Executive Branch have responded by attacking this commercial trade in illicit drugs, through regulation of the market backed by vigorous law enforcement. *See, e.g.*, Executive Office of the President, Office of National Drug Control Policy, *National Drug Control Strategy 2004*, at 31 (2004).

This case raises a fundamental issue: Will the Congress continue to be able to take *effective* action against the national problem of drug trafficking and abuse? In the decision here on appeal, the Ninth Circuit Court of Appeals held that

the federal government may not regulate what the court believed to be essentially "local" and "medical" illegal drug production and distribution. *Raich v. Ashcroft*, 352 F.3d 1222, 1228-34 (9th Cir. 2003). This ruling is inconsistent with this Court's Commerce Clause jurisprudence, which holds that even intrastate activities may be regulated by the federal government where, among other things, those activities have "a substantial relation to interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-60 (1995).

Marijuana is a commercial product, and its cultivation and distribution are "economic" activities, even when taking place within one state. No one state is able to take complete and effective action against this illegal market; rather, Congressional action is required. That action takes the form of a sophisticated and scientifically-based federal regulatory framework for drugs (whether medical or non-medical), including the statute at issue here – the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.* (2004). If local marijuana production, possession and distribution are excised from that regulatory framework, the nation's ability to address the narcotics epidemic will be seriously undermined.

ARGUMENT

I. MARIJUANA, WHETHER USED FOR "MEDICAL" PURPOSES OR NOT, IS PART OF THE LARGER, COMMERCIAL MARKET FOR DRUGS, AND AS SUCH MAY BE REGULATED BY CONGRESS UNDER THE COMMERCE CLAUSE.

The Ninth Circuit's ruling is inconsistent with this Court's Commerce Clause jurisprudence. Under Article I, Section 8 of the U.S. Constitution, Congress is empowered to "regulate Commerce with foreign Nations, and among

the several States." Although the Commerce Clause speaks only to interstate commerce, Article I, Section 8 also provides that Congress shall "make all Laws which are necessary and proper for carrying into Execution the foregoing Powers." Pursuant to the "Necessary and Proper" clause, this Court has held that even intrastate activities may be regulated by the federal government where, among other things, those activities have "a substantial relation to interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-60 (1995) ("Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.").

A. Marijuana Is a Commercial Product Subject to Congressional Regulation, Even When Used For So-Called "Medical" Purposes

In the post-New Deal era, this Court has struck down acts of Congress as exceeding the scope of the Commerce Clause only where the regulated activity lacks an "economic" character. Conversely, where federal regulations are targeted at economic activity, they have been sustained. *See Lopez*, 514 U.S. at 559; *United States v. Morrison*, 529 U.S. 598, 611 (2000). The Court of Appeals erred in holding that the cultivation, possession, and distribution of marijuana for "medical" purposes are not economic activities within the scope of the Commerce Clause. *Raich v. Ashcroft*, 352 F.3d 1222, 1228 (9th Cir. 2003). First, marijuana is an economic commodity, with a large and well-defined national market. Second, as a fungible, highly portable product, marijuana grown in one state can easily find its way to other states, necessitating a national system of regulation.

1. Marijuana Is an Inherently Commercial Product, With a Substantial National Market

Like all drugs, marijuana is an essentially commercial product. The fact that it may be used for alleged medical purposes certainly does not remove it from "commerce"; on the contrary, there are few commercial markets larger than that for "medical" products. In 2002, Americans spent over $1.3 trillion on personal healthcare and healthcare products; of that amount, $162.4 billion were spent on (legitimate) prescription drugs. Paulette C. Morgan, Congressional Research Service, *Health Care Spending: Past Trends and Projections*, Order Code RL31094, at CRS-1, -2 (2004).

As an illegal drug, marijuana is part of an equally commercial – albeit illegitimate – market. It is estimated that in 1998, Americans spent approximately $66 billion on illegal drugs, including $11 billion on marijuana alone. Executive Office of the President, Office of National Drug Control Policy, *What America's Users Spend on Illegal Drugs, 1988-1998*, at 1 (2000).[2] Marijuana is, in fact, the most widely used illegal drug in the United States; of the nearly 20 million current drug users in this country, approximately 14.6 million (75 percent) are using marijuana. Substance Abuse & Mental Health Servs. Admin., *2002 National Survey on Drug Use and Health* (2003).

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[2] The billions of dollars in drug proceeds produced here in the U.S. (including those from marijuana trafficking) have also spawned a massive money laundering industry, which uses our transportation and financial services networks to smuggle funds out of the country. *See* National Drug Intelligence Center, U.S. Dept. of Justice, *National Drug Threat Assessment 2004*, at 97-99.

The fact that some medical marijuana is ostensibly distributed free of charge or on a "non-profit" basis does not make this commodity any less "economic." The drug retains its value and its potential for sale, even when it is distributed for free and kept for ostensibly "medical" use. A bottle of the powerful opiate OxyContin, for example, does not lose its commercial potential while it sits in a patient's medicine cabinet.

Moreover, even "free" distribution can be economically motivated. Many companies provide certain goods or services free of charge to customers, often to build their reputations and market share; drug dealers have also been known to build their client base by providing "free samples" to prospective users. *See, e.g.*, Executive Office of the President, Office of National Drug Control Policy, *Pulse Check: Trends in Drug Abuse*, at 66 (2004) ("Some dealers distribute free drugs to 'testers' early in the morning, and then count on word-of-mouth to bring them more buyers throughout the day based on the quality or purity of the drug."). As the California court of appeals noted in 1998, permitting "non-profit" sales would allow businesses to use marijuana as an enticement to customers for other services. *People ex rel. Lungren v. Peron*, 59 Cal. App. 4th 1383, 1392-3, 70 Cal. Rptr. 2d 20, 27 (Cal. Ct. App. 1997).

2. Marijuana Is a Fungible, Portable Commodity That Can Easily Move From State to State

Marijuana is a highly fungible and portable product. As Judge Beam noted in his dissent in the opinion below, marijuana is a fungible, transferable, and therefore fundamentally economic product – even if a particular amount of marijuana has not actually been exchanged for

cash. *Raich*, 352 F.3d at 1242 ("While it is clear that plaintiffs did not propose to sell or share their marijuana with others similarly situated (or even not similarly situated), they *could*.") (emphasis in original).

Not only is marijuana a fungible product, it is extremely difficult to trace back to its source; there is currently no operational "marijuana signature" (source identification) program, as there is for cocaine and heroin. *See* National Drug Intelligence Center, U.S. Dept. of Justice, *National Drug Threat Assessment 2004*, at 48. This makes proof that the drug actually moved through interstate commerce extremely difficult, and overly burdensome to effective regulation – which is why Congress dispensed with this requirement when it enacted the CSA. *See United States v. Lopez*, 459 F.2d 949, 953 (5th Cir. 1972).

3. Effective Regulation of Marijuana Requires Federal Control of all Aspects of the Market, Including Initial Production and Distribution

As a valuable, fungible, portable, and untraceable product, marijuana presents significant challenges that can only be completely met by federal regulation. The individual states cannot adequately control marijuana trafficking. We live in a national, not a state or regional, market; if one state permits marijuana production to flourish within its borders, that production will quickly spill over into neighboring states. Stopping the flow would require each state to set up its own customs controls at its border, a solution that would be highly burdensome to the national economy, and likely to be ineffective. *See, e.g.*, Executive Office of the President, Office of National Drug

Control Policy, *2002 Final Report on the 1998 National Drug Control Strategy: Performance Measures of Effectiveness*, at 24-25 (2002) (reporting that, despite efforts of federal border and interdiction authorities, 94 percent of heroin, and 69 percent of cocaine targeted for the U.S. market entered the country).

The solution is provided by federal enforcement of the CSA. Unlike individual state regulators, the federal government can reach activity in every state. This Court has previously upheld, as valid enactments under the Commerce Clause, federal regulations of intrastate activities that affect more than one state. *See, e.g., Hodel v. Virginia Surface Mining and Reclamation Ass'n*, 452 U.S. 264, 282 (1981) (upholding environmental regulations). The CSA should be upheld on these grounds as well. *See Lopez*, 514 U.S. at 574 (Kennedy, J., concurring) ("Congress can regulate in the commercial sphere on the assumption that we have a single market and a unified purpose to build a stable national economy.").

B. Congress Has Created a Carefully Calibrated Regulatory Scheme for National Drug Markets (Including the Marijuana Market), Which Requires Effective Enforcement Even on the Local Scale

Congressional narcotics statutes are designed to deal with the local, national, and even international aspects of this enormous, complex drug market. As this Court has noted, a regulation of apparently local activity may be upheld as "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U.S. at 561. Examples of such regulatory

frameworks upheld by this Court include price controls and quotas for wheat production, *Wickard v. Filburn*, 317 U.S. 111, 128-29 (1942); grain storage regulations, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947); civil rights regulations of the public accommodations industry, *Heart of Atlanta Motel v. United States*, 379 U.S. 241, 261 (1964); prohibitions on "loan sharking," *Perez v. United States*, 402 U.S. 146, 156 (1971); national wage and salary restrictions, *Fry v. United States*, 421 U.S. 542, 547-48 (1975); and environmental restrictions on coal mining, *Hodel*, 452 U.S. at 283.

Congressional regulation of narcotic drugs falls into this category as well. To regulate the frequently intersecting legal and illegal drug markets, Congress has established a finely calibrated regulatory system over the course of nearly a century. That system provides for regulations of how drugs are tested, approved, and marketed as medicines; and enforcement against those who refuse to comply with the regulations.

1. Congressional Regulation of the Drug Testing, Approval, and Marketing Process

Congress began establishing the modern-day system of medical drug regulation in 1906, with the passage of the original Pure Food and Drug Act. Prior to that Act, America "was mired in near medicinal anarchy." *See* Andrea Barthwell, M.D., *Don't Fall For Pot-Smoking Con*, Hartford Courant, Apr. 30, 2004, *available in* http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=975. Traveling salesmen hawked "miracle medicines" that rarely actually cured anything; instead, they made patients feel better through the use of alcohol or opiates. *Id.*

This was the age of "patent medicines" which were heavily marketed and advertised with false claims as to their contents and efficacy. *See* Philip J. Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*, 25-30 (2003).

The 1906 Act created the agency that later came to be known as the U.S. Food and Drug Administration (FDA). *See* Hilts, *supra* at 74. The 1906 Act was superseded by the Food, Drug and Cosmetic Act (FDCA, 21 U.S.C. 301, *et seq.*) in 1938, which, for the first time, forced pharmaceutical companies to test their drugs for safety and efficacy, under the regulation of the FDA. *See* Hilts, *supra* at 95. The drug approval process under the FDCA requires rigorous scientific proof, careful review by the FDA's scientific staff, and the assurance that drugs will be marketed only for the specifically approved indications. *See Marijuana and Medicine: The Need for a Science-Based Approach, Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform*, 108th Cong , 2d Sess. (Apr. 1, 2004) (statement of Robert J. Meyer, M.D., Director, Office of Drug Evaluation II, Center for Drug Evaluation & Research, U.S. Food & Drug Admin.), at 2-7.

These Congressional actions are largely responsible for creating the modern market in safe, effective medicines. One historian argues that after the passage of the FDCA, a "revolution in medicine took place . . . [T]he pharmaceutical industry went from a handful of chemical companies with no interest in research and no medical staffs to a huge machine that discovered, developed, and marketed drugs of real use in treating disease." *Id.* Indeed, "rather than being merely a bureaucratic imposition on scientific progress, the FDA was arguably the co-inventor

of the clinical trial process . . . This is the process on which modern medicine founds most of its claims." Todd Seavey, *Regulation for Dummies: Is the FDA Necessary?*, Reason, Apr. 2004, at printed page 4.

2. Enforcement of Congressional Drug Regulations

Within a decade after passing the Pure Food and Drug Act, Congress passed the first federal drug enforcement law, the Harrison Narcotics Act, in 1914.[3] In 1970, Congress undertook a thorough revision of the federal narcotics laws, replacing them with the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.* Although drafted in the form of a criminal statute, the CSA "concerns an obviously economic activity," *United States v. Genao*, 79 F.3d 1333, 1337 (2d Cir. 1996), namely the black market in illegal (or illegally diverted) drugs. Many of the CSA's provisions govern the registration, labeling and packaging, production quotas, and record-keeping of those wishing to manufacture, distribute or dispense controlled substances. 21 U.S.C. 822-827 (2004). It is the "enforcement" side of the regulatory framework initially established by the FDCA.

Without effective law enforcement by DEA and similar agencies, it would be impossible for Congress to ensure that only safe and effective drugs are available to the public, and that those drugs are not diverted to the illegal black market. The FDA is not, by itself, capable of effectively carrying out

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[3] The Harrison Act and other early federal narcotics enforcement statutes were based on Congress' revenue powers. *See* Charles Doyle, Congressional Research Service, *Drug Smuggling, Drug Dealing and Drug Abuse: Background and Overview of the Sanctions Under the Federal Controlled Substances Act and Related Statutes*, Order Code 97-141 A, at CRS-1 and -2 (2003).

this enforcement role; instead, it relies on enforcement of the CSA by the DEA and other federal law enforcement agencies to defend the federal government's regulation of drugs. As a law enforcement agency, "DEA has the authority, expertise, and resources to interdict the illegal use of controlled substances." *See* Letter from Patrick Ronan, Assistant Commissioner for Legislation, U.S. Food and Drug Admin., to Rep. Mark E. Souder (July 1, 2004), at 3. Moreover, the CSA, as a statute primarily directed at criminal enforcement, is the more appropriate statute for enforcement actions, providing "greater penalties and requir[ing] proof of far fewer elements to establish a violation." *Id.*

Taken together, the FDCA and the CSA represent "a powerful 'social contract for drug use,' which established that potentially addictive (and abused) drugs would be available under a physician's prescription and only to treat illnesses other than addiction. . . . This approach to potentially abused medicines is now the standard throughout the world. It has served Americans admirably for most of the 20th century, separating medical from non-medical uses, labeling the contents of medicines, and subjecting medicines to scientific review for safety and efficacy." Robert L. DuPont, *Examining the Debate on the Use of Medical Marijuana*, 111 Proceedings of the Ass'n of American Physicians 166, 167 (Mar./Apr. 1999).[4]

[4] The fluid, global nature of the illicit drug market demands not simply a national strategy, but an international one. To that end, Congress has ratified a number of international narcotics treaties obligating signatory countries to take effective steps to control potentially dangerous drugs. *See, e.g.*, Multilateral Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, T.I.A.S. 6298; Multilateral Amendment of the Single Convention on Narcotic Drugs, Mar. 25,

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3. Federal Drug Regulation and Marijuana

The history of marijuana in this country illustrates the efficacy of federal drug regulations – and the necessity of their full enforcement. Before the era of modern science, marijuana, like alcohol and tobacco, was used as a "folk remedy" for numerous ailments over the centuries. *See* DuPont, *supra* at 167. In the 19th century, marijuana was marketed as a medicine in the form of "tinctures, extracts, and elixirs," as a remedy for "asthma, bronchitis, migraine headaches, depression, gonorrhea, uterine hemorrhage, and dysmenorrhea." Andrea Barthwell, Deputy Director, Executive Office of the President, Office of National Drug Control Policy, *Marijuana as Medicine?*, Testimony before the New England Governors' Summit on Drug Use, Oct. 8, 2003. Quality controls were virtually non-existent. *Id.*

In the modern era, however, botanical marijuana has never been able to pass the strict scientific standards adopted by Congress; as a result, it has never been approved by the FDA as a safe and effective drug. *See* Response of Amit K. Sachdev, Associate Commissioner for Legislation, U.S. Food and Drug Admin., to Rep. Mark E. Souder, Sept. 25, 2003, at 1. This is because marijuana is fundamentally bad for human health. *See, e.g.*, *Marijuana and Medicine: The Need for a Science-Based Approach,*

1972, 26 U.S.T. 1439, T.I.A.S. 8118; Multilateral Convention on Narcotic Drugs: Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, T.I.A.S. 9725. Among other things, the 1961 Treaty requires signatories (including the U.S.) to establish a single national agency to license and control all supplies of marijuana for medical or research purposes. *See* 1961 Treaty, art. 23, 28; *see also* International Narcotics Control Board, United Nations, *Report of the International Narcotics Control Board for 2003*, at 24 (reminding signatory countries that the 1961 Treaty requires the creation of a "national cannabis agency").

Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform, 108th Cong., 2d Sess. (Apr. 1, 2004) (statement of Nora Volkow, Director, National Institute on Drug Abuse) (detailing research into negative impacts of marijuana use on the human body, and noting that the drug is addictive); Eric A. Voth, *A Peek into Pandora's Box: The Medical Excuse Marijuana Controversy*, 22 Journal of Addictive Diseases 27, 36-38 (2003) (listing negative health effects of marijuana, including brain damage, lung damage, and heart disease).

While some research does suggest that certain components of marijuana, most notably THC, may be useful to treat certain conditions, the Director of NIDA also recently testified that "there is greater promise in purifying the active constituents of marijuana and developing alternate delivery systems, such as inhalers, rather than studying smoked marijuana." *See* Volkow Statement, at 6. In fact, the FDA has already approved pure THC in pill form (called dronabinol, or "Marinol") for some indications. *See* Eric A. Voth and Richard A. Schwartz, *Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana*, 126 Annals of Internal Medicine 791, 791-4 (1997). Contrary to the claims made by some pro-marijuana activists, the federal government permits and supports research into the therapeutic potential of marijuana and its components. *See* Volkow Statement, at 6-9. Pharmaceutical companies are also actively developing new treatments made from marijuana. *See, e.g., Researcher working on medical patch to deliver marijuana-like chemicals*, Aug. 20, 2003, Assoc. Press State & Local Wire, *available in* LEXIS/NEXIS (describing efforts to create a medical treatment delivering THC through the skin); Eric Bailey, *British Firm Holds Hope for Users of Medical Pot*, Los Angeles Times, Feb. 1,

2004, at B1 (describing experimental marijuana derivative known as Sativex). In short, federal regulation of marijuana is serving the interest of public health.

Through state medical marijuana laws and lawsuits such as this one, however, pro-marijuana activists are seeking to do an end-run around these important regulatory safeguards. According to the FDA, state laws purporting to legalize medical marijuana "are inconsistent with [FDA's] efforts to ensure that approved medications have undergone rigorous scientific scrutiny and FDA's approval process." *See* FDA Statement Re: Marijuana Legislation, provided to Rep. Mark E. Souder on July 7, 2004. In opposing recent legislation that would have prohibited the U.S. Department of Justice from fully enforcing marijuana laws in states purporting to legalize the drug's "medicinal" use, the FDA further stated that "DEA is the Federal agency with primary jurisdiction regarding enforcement actions relating to the sale or distribution of marijuana. FDA will continue to cooperate with DEA in these actions. . . . We reiterate that any legislation that would prevent the Department of Justice or the DEA from enforcing the CSA with respect to marijuana either generally or in specified States would not serve the interests of public health." *Id.*

C. Exempting So-Called "Medical" Marijuana From Federal Drug Regulations Would Seriously Undermine Their Effectiveness

In its opinion below, the Ninth Circuit refused to look at the problem of marijuana trafficking as a whole, or the impact that local production, possession, and distribution have on the drug trade. Instead, the court narrowed its focus to "a *separate and distinct class of activities:* the

intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes." *Raich*, 352 F.3d at 1228 (emphasis in original). By examining this "class of activities" in isolation from the overall marijuana trade, the court failed to see the effects that it might have on drug trafficking and law enforcement. The Ninth Circuit's error illustrates why this Court has warned against too narrow a focus on individual cases when examining a general regulatory statute. *See Lopez*, 514 U.S. at 558 ("where a general regulatory statute bears a substantial relation to commerce, the de minimum character of individual instances arising under that statute is of no consequence") (quoting *Maryland v. Wirtz*, 392 U.S. 183, 197 n. 27 (1968)) (italics and internal quote marks omitted). Individual courts can often underestimate or even fail to recognize what motivated Congressional action – namely, the importance of seemingly local phenomena to a national problem.

As reflected in its detailed findings in the CSA, Congress understood that to be effective, enforcement of drug regulations needs to reach all levels of the drug trade – including the initial production of the drug, and its "local" possession and distribution.[5] This policy is based on

[5] "The Congress makes the following findings and declarations:

. . .

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because –

(A) after manufacture, many controlled substances are transported in interstate commerce,

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the fact that often the most effective drug enforcement is that which goes to the initial source of the narcotics. As this Court has held, the Commerce Clause power "permits Congress to attack an evil directly at its source, provided the evil bears a substantial relationship to interstate commerce." *North American Co. v. Securities & Exchange Comm'n*, 327 U.S. 686, 705 (1946).

Permitting even the limited marijuana cultivation and distribution allegedly at issue in this case would undermine drug regulation by (1) giving drug traffickers a new strategy to evade arrest; (2) creating geographic "safe havens" for drug dealers to base their operations; (3) increasing the risk of diversion from "medical" use to purely recreational trafficking; (4) increasing the supply and lowering the price of marijuana; and (5) potentially

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic."

21 U.S.C. Sec. 801 (2004).

increasing the demand for the drug through reduced public perception of marijuana's harms. These practical considerations must be taken into account when evaluating Congress' power to deal with the narcotics trade. *See id.* ("And in using this great power, Congress is not bound by technical legal conceptions. Commerce itself is an intensely practical power. . . . To deal with it effectively, Congress must be able to act in terms of economic and financial realities.").

1. Creating a "Medical" Loophole for Marijuana Cultivation, Possession, and Distribution Would Give Drug Traffickers a New Strategem to Evade Arrest and Punishment

State medical marijuana laws undermine effective law enforcement, as drug traffickers can simply assert that their products are "medicinal" – forcing law enforcement authorities to prove otherwise. There is mounting evidence that current state medical marijuana laws are already being used as a cover for large-scale drug production and trafficking. In Oregon, for example, police discovered underground marijuana greenhouses with more than 3,500 plants, with room for 5,000 to 7,000 plants; the owners held state "medical marijuana cards" entitling them to possess the drug. *See* Beth Quinn, *Southern Oregon Police Raids Find 3,500 Marijuana Plants*, Portland Oregonian, Dec. 13, 2003, at C01. In Denver, Colorado, federal agents seized 800 marijuana plants from 3 homeowners, 2 of whom had state authorization to grow "medical" marijuana. Kirk Mitchell, *Feds Seize 800 Pot Plants*, Denver Post, June 3, 2004, at B-01. And just last month, the California Highway Patrol discovered a massive clandestine marijuana growing operation – with almost 2,000 plants

worth millions of dollars; medical marijuana activists, however, claimed that the marijuana was for "medical" purposes and was legal under Oakland city laws. Paul T. Rosynsky, *Big dispute in city pot bust*, Alameda Times Star, July 1, 2004, *available in* LEXIS/NEXIS. According to the U.S. Department of Justice, outlaw motorcycle gangs have applied for medical marijuana "caregiver" status, in an effort to legitimize their marijuana grow operations. *See* Letter from Robert F. Diegelman, Acting Assistant Attorney General for Administration, U.S. Dept. of Justice, to Paul Jones, Director, Justice Issues, General Accounting Office, dated Sept. 27, 2002, *reprinted in* General Accounting Office, *Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes*, Report No. GAO-03-189, at 57 (2002). In Nevada, a convicted drug dealer obtained a state "medical marijuana" registration card (purportedly to treat his "bipolar" mental condition), and began growing the drug and "sell[ing] or giv[ing]" it to "about 20 other medical marijuana patients through his enterprise, Primary Caregivers and Consultants." Ed Vogel, *Medical Marijuana: Working to smoke out abusers*, Las Vegas Review-Journal, Apr. 12, 2004, at 1B.

Exemptions for "small" amounts of marijuana can also be a boon for drug traffickers. Three ounces of marijuana, for example, can make anywhere from 90 to over 250 marijuana cigarettes, or "joints" – enough to supply a so-called "medical marijuana user" for a month. *See* Dan Kulin, *Number of joints possible with 3 ounces of pot debated: Question 9 argument becomes food for commercial*, Las Vegas Sun, Oct. 15, 2002, 2002 WL 101210627. Where small amounts are presumed to be beyond the reach of the law, drug dealers will simply distribute drugs in those amounts so as to escape arrest. *See, e.g., Costa*

Rica: Review, Americas Review World of Information, Sept. 23, 2002, 2002 WL 100885937 (since Costa Ricans are allowed to possess small amounts of drugs, it makes it very difficult to stop dealing in drugs like crack cocaine).

2. Allowing Individual States To Immunize Marijuana Possession From Federal Regulation Would Create Geographic "Safe Havens" For Drug Traffickers

If certain states are permitted to simply "opt out" of federal drug regulation, they will quickly become a haven for drug traffickers. Drug trafficking organizations typically seek out venues where the drug laws, and/or the enforcement of those laws, are weaker; the drugs they manufacture or import in those areas can then be smuggled into areas where drug enforcement is more stringent. This has been especially obvious in the international arena. For example, when Congress passed stricter laws against the diversion of the precursor chemicals for methamphetamine production (such as pseudoephedrine), drug traffickers turned to Canada (where precursor chemical regulation was much weaker) as their source of supply. *See* Office of International Intelligence, U.S. Drug Enforcement Administration, and Criminal Intelligence Directorate, Royal Canadian Mounted Police, *Chemical Diversion and Synthetic Drug Manufacture*, at printed pages 1, 8. Similarly, lax Canadian laws and enforcement against marijuana growing have made the province of British Columbia a center of high-potency marijuana production. *See* Quentin Hardy, *Inside Dope*, Forbes, Nov. 10, 2003, at 146 (noting that in British Columbia only one-fifth of marijuana busts result in incarceration and the average sentence is only four months). This high-potency

marijuana is being smuggled into the U.S. *See* U.S. Department of State, *International Narcotics Control Strategy Report, 2003* (2004).

In Europe, lenient drug policies have made the Netherlands a haven for drug smuggling. *See, e.g.*, Justin Sparks, *Dutch Law Could Unleash Cocaine Flood In Britain*, London Times, Feb. 1, 2004, at 24; Ciarin McGuigan, *Mule be sorry; Dutch decision to 'let off' drug smugglers could lead to growth in trafficking here*, Belfast Telegraph Newspapers – Sunday Life, Mar. 14, 2004, *available in* LEXIS/NEXIS (Dutch policy of releasing drug smugglers at its airports carrying "normal" amounts of illegal drugs has sparked neighbors' fears that the Netherlands will become the preferred European Union gateway for narcotics). *See also* Anthony Browne, *Dutch drug café ban puts British noses out of joint*, London Times, Oct. 25, 2003, Overseas news section, at 5 (reporting on Dutch government's consideration of plan to forbid foreigners from accessing legal marijuana shops in the Netherlands, in part to stop cross-border trafficking by German drug dealers who purchase marijuana in the Netherlands and then drive it to Germany).

This problem is exacerbated by the fact that in states and localities that have attempted to legalize marijuana, state and local officials (facing local political pressures) are increasingly hostile to federal drug policies. For example, one California sheriff recently stated that he would, if necessary, actually remove seized marijuana from his department's evidence locker and give it to a friend in medical need. *See* Josh Richman, *Cops say feds' focus 'misplaced'*, Oakland Tribune, May 25, 2003, 2003 WL 8915341. According to the U.S. Department of Justice,

state officials are often refusing to prosecute obvious cases of drug dealing out of deference to state "medical marijuana" laws, and in one instance a local district attorney even ordered a county detective to arrest a DEA agent if the agent seized marijuana plants purportedly belonging to a "patient". *See* Diegelman Letter, *supra* at 56.

Furthermore, if drug production is permitted to take root in a community, that community can quickly become economically dependent on the drug – putting additional pressure on local governments to turn a blind eye to the problem. *See* Hardy, *supra* (reporting that marijuana has become Canada's most valuable agricultural crop, with even the legitimate British Columbian economy increasingly dependent on the profits from it). In fact, many so-called "medical" marijuana sellers now openly operate as businesses in California (which has the most permissive medical marijuana law). In Rosewood, California, a store sells strains of marijuana known as "Romulan," "White Rhino," "Acapulco Gold," and "Placer Gold" for $200-$320 per ounce, reportedly with the tacit approval of the local chief of police. *See* Art Campos and Jocelyn Wiener, *Store for medical pot opens in Roseville*, Sacramento Bee, Jan. 31, 2004, at A1. In Oakland, California, a dozen "cafes" selling purported medicinal marijuana (at least one owner claiming to serve 7,000 "patients") were in operation by the end of 2003, earning it the nickname "Oaksterdam"; in 2004, the city attempted to limit the number of stores by issuing marijuana "business permits" (in return for a $20,000 annual fee). *See* Jean Marbella, *Marijuana 'du jour' in Oakland*, Baltimore Sun, Nov. 28, 2003, at 1A; Laura Counts, *Medical marijuana merchant defies Oakland order to close*, Alameda Times-Star, June 2, 2004, *available in* LEXIS/NEXIS.

Nor can state medical boards in such states be relied on to provide effective regulation. As one commentator has observed, medical marijuana initiatives "have created serious regulatory dilemmas for state regulatory boards." Voth, *A Peek into Pandora's Box* at 27. Despite their mission to oversee the practice of medicine in their respective states, many of these boards disavow any responsibility to determine whether drugs are safe or effective. *See Marijuana and Medicine: The Need for a Science-Based Approach, Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform*, 108th Cong., 2d Sess. (Apr. 1, 2004) (statement of James D. Scott, Member and Past Chair, Oregon Board of Medical Examiners), at 2, ("No one representing the [Board] is prepared to give any testimony regarding the scientific or medicinal value of marijuana, or any sociopolitical issues regarding marijuana. These issues are beyond our jurisdiction."); Letter from Joan M. Jerzak, Chief of Enforcement, Medical Board of California, to Rep. Mark E. Souder, May 11, 2004, at 1, 2 ("The Board does not establish 'procedures' which physicians must follow, nor does it take a position with regard to specific medications. . . . [I]t is not for the Board to determine which medical conditions may be appropriately treated with marijuana.").

3. Legalizing "Medical" Marijuana Will Increase the Chances of Diversion to Purely Recreational Use

By increasing the amount of marijuana, and the number of "legitimate" uses for it, state medical marijuana laws increase the chance that the drug will be diverted to purely recreational uses. The more legally available any

drug is the more indications it is approved for, and the greater the quantities of the drug in legitimate channels, the higher the rate of illegal diversion, trafficking and abuse will be. *See* Responses of Thomas W. Raffanello, Special Agent in Charge, Miami Division, Drug Enforcement Administration, to Questions from Rep. Mark E. Souder, May 24, 2004, at 2; Letter from Amit K. Sachdev, Associate Commissioner for Legislation, U.S. Food and Drug Admin., to Rep. Mark E. Souder, Apr. 26, 2004, at 2. The diversion of legal (but controlled) medical drugs into illegal uses is widespread, rivaling the market for strictly illegal drugs. For example, nationwide in 1993, people spent an estimated $25 billion on prescription drugs in the illegal market, compared with $31 billion on cocaine, including crack. *See* National Drug Strategy Network, *Prescription Drug Abuse Rivals Illicit Drug Abuse, Some See Double Standard in Law Enforcement*, New Briefs – Drug Use Trends (Oct. 1996). Abuse of legal prescription drugs, such as the opiate OxyContin, is on the rise; by 2001, prescription pain killers were second only to marijuana as the most abused category of drug. *See* National Survey on Drug Use and Health, *Nonmedical Use of Prescription Pain Relievers*, at 2 (2004).

Once a drug can be legally obtained, drug dealers and addicts have an increased number of avenues to obtain it – including prescription fraud (forging prescriptions; visiting multiple doctors to obtain prescriptions, often called "doctor shopping"; and altering prescriptions to increase the quantity); and outright theft or robbery from pharmacies (often performed by pharmacy workers themselves). *See* Julie Wartell and Nancy G. La Vigne, Office of Community Oriented Policing Services, U.S. Dept. of Justice, *Prescription Fraud* (2004), at 2-3. Those obtaining these drugs via fraud can, and do, ship them for profit to other

states. *See, e.g.*, Drug Enforcement Administration, *OxyContin: Pharmaceutical Diversion*, at printed page 5 (2002) (reporting DEA investigation into individual who took advantage of a severe medical condition to obtain legitimate prescriptions for OxyContin and other oxycodones from physicians in Arizona and California; he then shipped the pills – approximately 8,000 to 9,000 over the course of a year – via FedEx to another individual in Maryland for distribution).

The risk of "medical" marijuana being diverted is heightened by the fact that certain doctors have been consistently expanding their list of marijuana-treatable "conditions." One doctor, Frank H. Lucido, reports writing medical marijuana recommendations for 348 patients over a six-month period in 2002, for a wide range of conditions, including headaches, chronic anxiety, depression, insomnia, post-traumatic stress disorder, asthma, bipolar disorder, attention deficit disorder, vertigo, tinnitus, restless leg syndrome, phantom limb pain, and obsessive compulsive disorder. Frank H. Lucido and Mariavittoria Mangini, *Implementation of the Compassionate Use Act in a Family Medical Practice: Seven Years' Clinical Practice*, O'Shaughnessy's Journal of the California Cannabis Research Medical Group, Spring 2004, at 3. Claudia Jensen, a California pediatrician, has stated that she has recommended marijuana to teenagers with attention deficit disorder, despite acknowledging that "the science is lacking to justify some of her unorthodox uses." Daniel Costello, *Unorthodox uses for medical marijuana*, Los Angeles Times, Feb. 23, 2004, at F3; *see also Marijuana and Medicine: The Need for a Science-Based Approach, Hearing Before the Subcomm. on Criminal Justice, Drug Policy & Human Resources of the House Comm. on Government Reform*, 108th Cong., 2d Sess. (Apr. 1, 2004)

(statement of Claudia Jensen, M.D.), at 7-9. These cases are not isolated incidents. A 2003 study of AIDS patients using marijuana showed that less than one third smoked the drug even to relieve pain; 57 percent smoked to relieve anxiety or depression, while 33 percent admitted they smoked for "recreational" reasons. Sara Zaske, *Study: Many HIV patients use pot for mental health*, San Francisco Examiner, June 9, 2003, *available in* http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=975. In Oregon, of the 10,196 patients registered with the state's medical marijuana program, only 335 were listed as suffering from cancer; only 221 with HIV/AIDS; only 198 with glaucoma; and only 438 with cachexia; by contrast, 8,711 patients listed "pain" as their reason for taking the drug. *See* Oregon Department of Human Services, *Oregon Medical Marijuana Program Statistics* (July 1, 2004).

Other pro-marijuana doctors are, moreover, also writing very large numbers of "recommendations" for marijuana. According to one estimate, as of spring 2004, 100,000 marijuana recommendations had been issued in California, almost half written by only 12 physicians in California – all associated with a group known as the California Cannabis Research Medical Group. Fred Gardner, *Encouraged by 9th Circuit's Conant Ruling, More California Doctors Approve Cannabis Use*, O'Shaughnessy's Journal of the California Cannabis Research Medical Group, Spring 2004, at 1. One doctor alone acknowledged writing approximately 8,000 such recommendations. *Id.* at 7. In Oregon, Dr. Phillip E. Leveque was recently suspended by the state medical board for writing 4,000 medical marijuana authorizations – approximately 40 percent of the total such authorizations in the state – often without conducting any physical examination or even personally meeting with his patients. *See* Kramer, Andrew, *Oregon doctor's license*

suspended for signing marijuana cards, Associated Press, Mar. 5, 2004, *available in* LEXIS/NEXIS.

4. The Aggregate Effect of Even Individual Cultivation of "Medical" Marijuana Justifies Federal Regulation

Even when marijuana never actually enters the immediate stream of commerce, it may still be regulated to prevent it from impacting the broader market. This Court has repeatedly held that Congress may look to the total, aggregate effect of many apparently small, local transactions on interstate commerce and federal regulations thereof. *See, e.g., Wickard*, 317 U.S. at 128-29 (aggregate effect of home-grown and personally consumed wheat); *Katzenbach v. McClung*, 379 U.S. 294, 301 (1964) (aggregate effect of many individual acts of racial discrimination at restaurants); *Perez*, 402 U.S. at 154-55 (aggregate effect of acts of loan sharking); *Fry*, 421 U.S. at 547 (aggregate effect of wage increases for state employees).

As was the case in *Wickard*, marijuana grown and consumed, even locally by purported "medical" users, can exert a significant effect on the traffic in the drug, by adding to the nation's marijuana supply while reducing demand on the immediate market. The result will be lower overall prices on the black market. *See Proyect v. United States*, 101 F.3d 11, 14 n. 1 (2d Cir. 1996) ("[T]he cultivation of marijuana for personal consumption most likely does substantially affect interstate commerce. This is so because 'it supplies a need of the man who grew it which would otherwise be reflected by purchases in the open market.'") (citing *Wickard*, 317 U.S. at 128); *see also* Drug Enforcement Administration, *Illegal Drug Price and Purity Report* (Apr. 2003) ("A decrease in drug price

typically indicates an increase in availability, and, conversely, a price increase usually indicates a decrease in supply."). This would undermine a key component of the federal government's anti-marijuana strategy, namely to increase the price of illicit drugs, resulting in a reduction in the demand. *See* Office of National Drug Control Policy, *National Drug Control Strategy 2004*, at 31 ("The main reason supply reduction matters to drug policy is that it makes drugs more expensive, less potent, and less available. Price, potency, and availability are significant drivers of both addicted use and casual use.").

5. Legitimizing "Medical" Use of Marijuana Will Potentially Increase the Demand For the Drug, by Reducing Public Perception of Marijuana's Harms

Repeated claims of marijuana's "medicinal" value, coupled with the apparent ratification of those claims by state medical marijuana laws, have lowered the public perception of marijuana's scientifically demonstrated harmfulness – particularly among young people. *See* Andrea Barthwell, Deputy Director, Office of National Drug Control Policy, *Marijuana Is Not Medicine*, Chicago Tribune, Feb. 17, 2004, at C19 ("Children entering drug abuse treatment routinely report that they heard that 'pot is medicine' and, therefore, believed it to be good for them."). These public perceptions can have a significant impact on marijuana usage rates. *See, e.g.*, Wilson M. Compton, et al., *Prevalence of Marijuana Use Disorders in the United States, 1991-1992 and 2001-2002*, 291 JAMA 2114, 2119 (2004) (reporting study demonstrating that decreases in the perceived risk of harmfulness and in

disapproval of marijuana use can explain the recent rise in marijuana use by young people).

D. If Congress Is Prevented From Regulating Local Production, Possession, and Distribution of Marijuana, Its Ability To Regulate Other Drugs Will Be Placed in Jeopardy

A ruling that the federal government may not regulate local production, possession, and distribution of "medical" marijuana would have far-reaching implications for the regulation of all drugs, both legal and illegal. A vast number of controlled substances may be produced in the home, including methamphetamine, GHB, and MDMA ("ecstasy"). *See* Drug Enforcement Administration, *Drug Trafficking in the United States* (2001). And virtually all drugs have at least some putative "medical" uses; for example, cocaine and heroin were long used as anaesthetics, methamphetamine as a stimulant, and for many years LSD and ecstasy were used in psychotherapy.

This scenario is not as unlikely as it may seem. In fact, many of the same proponents of medicinal marijuana have actively sought to force the approval of some of these other drugs as "medicines." *See, e.g., Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881 (1st Cir. 1987) (petition by pro-medical marijuana advocate Dr. Lester Grinspoon to remove ecstasy from Schedule I of CSA). In several foreign countries, physicians may now prescribe heroin to addicts as part of a medical practice known as "maintenance," and the same may soon be done for cocaine. *See, e.g.*, Dan Gardner, *Free junk for junkies*, Ottawa Citizen, Jan. 18, 2004, at C3; *Doctors push for cocaine prescription*, Swissinfo, June 3, 2004, *available at* http://www.swissinfo.org/sen/Swissinfo.html?siteSect=105&sid=4958011. If a

state were to attempt to approve these or any other currently controlled drugs for "medical" use, it would set up the same federal-state conflict present here.

CONCLUSION

Describing the 19th century age of "quack medicines," one historian writes that, "The market in medicines, without any regulation, was essentially the same as the only market today with no regulation – the trade in heroin, cocaine, and other drugs. The supply was unreliable, the purity suspect, the price high and variable, and the corrupted substances sometimes fatal." Hilts, *supra* at 27. Proponents of "medical" marijuana would take us full circle, "back to a time before the passage of the Pure Food and Drug Act." Barthwell, *Marijuana as Medicine?* Through its power to regulate the interstate commerce in medical drugs, Congress has the responsibility to protect the American public from such a foolish step backwards. That power, and that responsibility, are fully consistent with the Constitution and should not be denied. The decision of the Court of Appeals should be reversed.

Respectfully submitted,

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No. 03-1454

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AMICUS CURIAE BRIEF OF THE MARIJUANA POLICY PROJECT AND RICK DOBLIN, Ph.D. IN SUPPORT OF THE RESPONDENTS

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The Marijuana Policy Project (MPP) and Rick Doblin, Ph.D. respectfully submit this brief as *amici curiae* in this case. Letters from Petitioner and Respondents granting consent to the filing of this brief have been filed with this Court.[1]

[1] Pursuant to S.Ct. Rule 37.6 counsel certifies that no counsel for a party authored any part of this brief. No person or entity other than *amici* made a monetary contribution to the preparation or submission of the brief.

MPP (www.mpp.org) is a non-profit, public interest advocacy organization representing more than 1,000 seriously ill people throughout the nation who are struggling to obtain legal access to medical cannabis. Since 1995, MPP and several of its seriously ill clients have met with officials from the FDA, the National Institutes of Health, and the National Institute on Drug Abuse (NIDA). MPP representatives have also testified before the National Academy of Sciences' Institute of Medicine (IOM) and the American Medical Association House of Delegates. MPP's clientele, like thousands of other patients nationwide, must choose between suffering or following their doctors' orders to use medical cannabis—even though the latter may result in a federal prison sentence. Consequently, MPP is exhausting all options to provide a legal avenue through which its clients may obtain and use medical cannabis. Rob Kampia is the co-founder and executive director of MPP.

Rick Doblin has a Ph.D. in Public Policy from the Kennedy School of Government, Harvard University. He is the founder and current director of the Multidisciplinary Association for Psychedelic Studies (MAPS, www.maps.org), a non-profit membership-based research and educational organization and pharmaceutical company that works to develop cannabis and other Schedule I drugs into Food and Drug Administration (FDA)-approved prescription medicines. MAPS helped support the successful five-year struggle of Dr. Donald Abrams, University of California-San Francisco, to obtain permission to conduct research into the effects of smoked cannabis in HIV+ subjects. Dr. Abrams's study, which enrolled the first subject in 1998, was the first FDA-approved study of the medical use of smoked cannabis in a patient population in twelve years. MAPS holds the only Orphan Drug designation granted by the FDA for any medical use of the cannabis plant itself, specifically in the treatment of AIDS patients suffering from HIV-related wasting syndrome. MAPS thus has a commercial interest in developing the

cannabis plant into an FDA-approved prescription medicine for AIDS-wasting, and potentially for other clinical indications as well.

A prerequisite for any practical, privately-funded, cannabis drug development program is access to independently selected strains of cannabis and control over issues of cost and timely availability. For the last several years, MAPS has offered a grant to Prof. Lyle Craker, University of Massachusetts at Amherst (UMass Amherst), Director, Medicinal Plant Program, Department of Plant and Soil Sciences, to establish a small medical cannabis production facility to grow high-potency cannabis for use in FDA and DEA-approved protocols. Prof. Craker first applied for a license to the Drug Enforcement Administration (DEA) in June 2001, and is still waiting for a decision. MAPS has also sponsored laboratory research into the use of a vaporizer device, a non-smoking delivery system which heats the marijuana plant but doesn't burn it, releasing cannabinoids without toxic byproducts of combustion. The development of such devices was recommended by the Office of National Drug Control Policy-funded Institute of Medicine report. As of October 12, 2004, an application submitted on June 24, 2003 to NIDA from Chemic Laboratories, working under contract to MAPS, to purchase 10 grams of cannabis for further vaporizer research, has languished for over fifteen months without a response. An application from Chemic to the DEA, also submitted on June 24, 2003, to import 10 grams from the Dutch Office of Medicinal Cannabis has also not received a response. As a result of the lack of response, on July 21, 2004, MAPS filed a lawsuit against DEA and a separate one against HHS/NIH/NIDA, arguing unreasonable delay under the Administrative Procedures Act and claiming federal obstruction of its privately-funded cannabis drug development research effort.

SUMMARY OF THE ARGUMENT

The federal government, specifically NIDA of the U.S. Department of Health and Human Services (HHS), retains a restrictive and unnecessary monopoly over the only supply of cannabis that is currently allowed to be used in FDA-approved clinical trials. DEA sustains this monopoly by refusing to license any privately-funded production facilities. HHS and NIDA have exercised this monopoly over cannabis so as to impede the normal drug development process contemplated by Congress. Most recently, NIDA and HHS have unreasonably imposed an additional layer of regulatory review over privately funded clinical research with cannabis. No other Schedule I drug has to endure such an obstacle course.

In the instant case, this Court is being asked to decide whether patients have a constitutional right to use cannabis despite the Controlled Substances Act, 21 U.S.C. §801 *et seq*. Amici urge the Court to keep in mind that the FDA drug development process, the most direct and appropriate method for authorizing the provision of cannabis to patients with a legitimate, medical need for the drug, has been politically hobbled. The lack of FDA-approval of cannabis as a prescription medicine is due, in large part, to the systematic hindrance of scientific research by governmental agencies over the last several decades. The Court should not rule against patients' constitutional rights to use cannabis based on the illusion of a well-functioning FDA-approval process. Executive branch obstructionism has made it necessary for severely ill patients to assert their constitutional rights in order to obtain relief from life-threatening and disabling conditions.

THE ARGUMENT

I. ASSERTING PATIENTS' CONSTITUTIONAL RIGHTS TO USE CANNABIS IS THE ONLY REASONABLE ALTERNATIVE GIVEN THE GOVERNMENT'S OBSTRUCTION OF FDA-APPROVED RESEARCH INTO THE POTENTIAL THERAPEUTIC USES OF CANNABIS

A. An Agency of the Federal Government Has a Monopoly on the Legal Supply of Cannabis for Use in FDA-Approved Research.

The Single Convention on Narcotic Drugs, to which the United States is a Party, regulates the manufacture of cannabis within the boundaries of the signatory nations.[2] Under Article 23 2(e) of the convention, a private, non-governmental organization can obtain permission from a Party to grow cannabis for licensed medical uses without the Party coming into violation of any of the provisions of the Convention. The non-governmental producer would not need to sell its output to the government and could distribute its stocks for medical purposes to the extent that it was licensed to do so. In the United States, NIDA has a monopoly on the supply of FDA-approved research-grade cannabis for use in human subjects.[3] Sponsors of research into the medical uses of cannabis cannot at present manufacture their own supplies of research material but must instead petition to purchase federal supplies at cost from NIDA.[4]

[2] Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407 (entered into force in the United States on June 24, 1967), available at http://www.incb.org/e/ind_ar.htm.

[3] NIDA contracts with the University of Mississippi to grow cannabis for research purposes, under the direction of Professor Mahmoud El-Sohly. The University of Mississippi facility holds the only license issued by the DEA for the production of cannabis for human consumption.

[4] FDA has not permitted researchers to use seized cannabis for research purposes due to uncertain purity and the inability to conduct subsequent studies with a standardized and replicable product.

The NIDA monopoly has been an impediment to objective and accurate scientific research. NIDA's institutional mission is to sponsor research into the understanding and treatment of the harmful consequences of the use of illegal drugs and to conduct educational activities to reduce the demand for and use of these illegal drugs.[5] NIDA's mission makes it a singularly inappropriate agency to be responsible for expeditiously stewarding scientific research into potential beneficial medical uses of cannabis. Furthermore, as with many monopolies, the quality of its product is low,[6] and access is restricted.

Accordingly, members of the medical community have opposed NIDA's policies relating to the supply of cannabis for scientific research into its potential medical uses. In December 1997, the AMA House of Delegates resolved "[t]hat the AMA urge the National Institutes of Health (NIH) to implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research into the medical utility of marijuana."[7] The House of Delegates stressed that "marijuana of various and consistent strengths and/or placebo" should be supplied by NIDA to

[5] See website of the National Institute on Drug Abuse, http://www.drugabuse.gov/about/AboutNIDA.html.

[6] MAPS and California NORML conducted a scientific study of the potency of cannabis used by patients across the country. This potency was then compared to the average potency of the cannabis that NIDA provides to the seven remaining patients who are part of the Compassionate Investigational New Drug program. Patients preferred cannabis that was roughly three to four times more potent than what NIDA supplies. The primary advantage of more potent cannabis is that it enables patients to inhale less smoke and particulate matter per unit of therapeutic cannabinoids. Dale Gieringer, Ph.D. *Medical Cannabis Potency Testing Project*, 9 MAPS, Autumn 1999, available at http://www.maps.org/newsletters/v09n3/09320gie.html, at 20-22.

[7] Council on Scientific Affairs, AMA House of Delegates, Report 10 - Medical Marijuana, Recommendations (1997).

clinical researchers who have received FDA approval, "regardless of whether or not the NIH is the primary source of grant support.[8] However, NIDA has resisted supplying research cannabis to MAPS's privately funded studies, which has limited research and hobbled the process by which cannabis could become available as a prescription medicine.

In contrast, in England, which is also a Party to the Single Convention, the Home Office granted a license to GW Pharmaceuticals, a non-governmental for-profit corporation, to grow cannabis for the manufacture of cannabis extracts to be used in clinical trials.[9] Since that time, GW has completed several Phase III clinical trials with its marijuana extract and has entered into marketing agreements for this product. [10] The International Narcotics Control Board (INCB), which monitors member nations' compliance with international drug control treaties, has never objected to the British Home Office licensing of GW Pharmaceuticals to grow cannabis, either in any of its annual reports or any other publications, letters, or meetings.

B. FDA-Approved Research into the Therapeutic Uses of Cannabis Has Been Blocked by NIDA and DEA.

1. *Government opposition has deterred and limited objective scientific studies into the beneficial uses of cannabis.*

Ideally, after a physician has determined that a patient has a medical need for the use of the cannabis plant, the patient should be able to obtain it in the form of an FDA-approved

[8] *Id.*

[9] *See* website of GW Pharmaceutical company, www.gwpharm.com/faqs.asp#faqs1_6.

[10] *See* website of GW Pharmaceutical company, http://www.gwpharm.com/news_press_releases.asp.

prescription medicine that is standardized for purity and potency. For this outcome to be realized, a pharmaceutical company must first submit to FDA sufficient scientific data proving safety and efficacy in a specific patient population, with the data gathered in controlled clinical trials conducted with prior approval of the FDA and DEA. [11]

Despite persisting interest in the medical research community into the exploration of the medical uses of cannabis, not one single patient in the United States received cannabis in the context of an FDA-approved study during the 12-year period between 1986—when the last of the state studies into the use of smoked cannabis in controlling nausea and vomiting in cancer chemotherapy patients concluded[12]—and 1998, when Dr. Donald Abrams at the University of California-San Francisco administered smoked cannabis to the first HIV+ subject in his groundbreaking AIDS-wasting study.[13] Dr. Abrams had to struggle for five years to obtain permission to conduct his study, three years of which were involved with a fruitless effort to obtain cannabis from NIDA for his study after his initial protocol had been approved by FDA.[14] In May 1995, MAPS even tried to enter into a contract with Prof. Mahmoud El-Sohly, Director of NIDA's University of Mississippi cannabis farm, to produce cannabis for Dr. Abrams's study. Prof. El-Sohly was initially interested in exploring this idea but eventually declined, presumably so

[11] *See* Food and Drug Administration, Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (1998), *available at* http://www.fda.gov/cder/guidance/1397fnl.pdf

[12] R. Randall, 2 Marijuana, Medicine & the Law, 250. The States were California, New York, New Mexico, Tennessee, Georgia, Michigan and Washington.

[13] Donald Abrams, *Medical Cannabis: Tribulations and Trials*. 30 J. of Psychoactive Drugs, Apr.-Jun. 1998, at 163-69.

[14] *Id.*

as to not upset NIDA, his primary funder. Following and perhaps precipitated by California's 1996 passage of Proposition 215, which provided legal access to cannabis for patients whose physicians recommended it to them, NIDA indicated to Dr. Abrams that it might be willing to work out some arrangement whereby his long dormant FDA-approved study could go forward. In order to proceed at all, NIDA demanded that Dr. Abrams transform his FDA-approved protocol, designed to assess safety and efficacy in AIDS-wasting patients, into a safety study primarily evaluating the risks of cannabis in AIDS patients who did not suffer from AIDS-wasting syndrome.[15] Dr. Abrams and MAPS decided to accept NIDA's offer in order to start the research effort.

2. *Federal agencies have blocked the supply of cannabis for clinical research through unreasonable delay of applications.*

DEA and NIDA have further crippled research of medicinal cannabis by stalling the applications of parties interested in providing cannabis to researchers conducting FDA-approved studies. These agencies have resisted attempts to manufacture research cannabis as well as attempts to import it. Delays in the processing of applications have left parties unable to proceed with research or to appeal an adverse decision and have therefore obstructed the FDA approval process that Congress intended to make safe and effective medicines available to the public.

In June 2001, Prof. Lyle Craker, UMass Amherst, Director, Medicinal Plant Program, Department of Plant and Soil Sciences, with sponsorship from MAPS, applied to DEA for a

[15] Letter from Dr. Alan I. Leshner, Director of NIDA to Dr. Donald Abrams (Apr. 19, 1995), *available at* http://www.maps.org/mmj/leshner.html; Letter from Dr. Donald Abrams to Dr. Alan I. Leshner, Director of NIDA (April 28, 1995), *available at* http://www.maps.org/mmj/abrams.html.

license to establish a small medical cannabis production facility to supply high-quality research material to researchers with FDA and DEA-approved protocols.[16] More than three years later, Prof. Craker has still not received a decision on his application and remains stuck in a bureaucratic morass that prevents him from enabling research to study the potential beneficial uses of cannabis.

A chronology of the path of Prof. Craker's application illustrates the obstructionism that characterizes the inadequate process for furthering medical cannabis research. In December 2001, Prof. Craker was told by DEA that his application was lost. In February 2002, DEA refused to accept a photocopy of the application since it lacked an original signature, DEA having claimed to have lost the original document. On June 6, 2002, five Massachusetts Congressional Representatives sent a letter to DEA Administrator Asa Hutchinson expressing support for the licensing of a privately-funded cannabis production facility.[17] On July 1, 2002, DEA Administrator Asa Hutchinson replied to the Congressmen, stating DEA opposition to private production facilities based on supposed restrictions imposed by US international treaty obligations.[18] Later in July 2002, DEA returned the original application to Prof. Craker, unprocessed, with no individual's name on the return address or cover note, and with a DEA date-stamp showing that it had been received by DEA in June 2001. In August 2002, Prof. Craker re-

[16] Timelines and supporting documents available at www.maps.org/mmjfacility.html.

[17] Letter from United States Congressmen Michael E. Capriano, William D. Delahunt, Barney Frank, James P. McGovern, and John W. Oliver to Asa Hutchinson, DEA Administrator (June 6, 2002), *available at* http://www.maps.org/mmj/mmjfacility.html.

[18] Letter from Asa Hutchinson, DEA Administrator, to Congressman Barney Frank (Jul. 1, 2002), *available at* http://www.maps.org/mmj/mmjfacility.html.

submitted his original application, along with an analysis of U.S. international treaty obligations demonstrating that private production facilities were not prohibited.[19] On December 16, 2002, two DEA agents traveled to UMass Amherst to meet with Prof. Craker and senior UMass Amherst officials. The DEA agents encouraged them to withdraw the application, which they declined to do.

It was not until March 4, 2003, more than 20 months after his original application was filed, that Prof. Craker received his first direct written reply from DEA, from Mr. Frank Sapienza, Chief, Drug and Chemical Evaluation Section.[20] Mr. Sapienza reported that DEA considered NIDA's supply to be adequate for the research community and that DEA was "not persuaded" by Dr. Russo's December 30, 2002 letter [21] complaining about the low quality of NIDA material and discussing NIDA's refusal to supply him with cannabis for his FDA-approved protocol. Mr. Sapienza told Prof. Craker that in order for DEA "to further consider [his] application," he would need to submit "credible evidence" supporting his assertion that researchers were not adequately served by NIDA cannabis.[22] Prof. Craker responded to this request on June 2, 2003. In October, 2003, DEA again heard from elected representatives in support of Prof. Craker's application when Massachusetts Senators Edward Kennedy and

[19] The legal analysis was prepared pro-bono by lawyers with the D.C. law firm of Covington & Burling, in association with the American Civil Liberties Union Drug Policy Litigation Project. Their analysis is available at http://www.maps.org/mmj/mmjfacility.html.

[20] Letter from Frank Sapienza, Chief, DEA Drug and Chemical Evaluation Section, to Prof. Lyle Craker (Mar. 4, 2003), *available at* http://www.maps.org/mmj/mmjfacility.html.

[21] Letter from Dr. Ethan Russo to Mr. Simes, Drug Enforcement Administration (Dec. 30, 2002), *available at* http://www.maps.org/mmj/mmjfacility.html.

[22] *Id.*

John Kerry sent a letter stating their opposition to the NIDA monopoly on research cannabis. The Senators noted that lack of adequate competition "jeopardizes important research into the therapeutic effects of marijuana for patients undergoing chemotherapy or suffering from AIDS, glaucoma, or other diseases."[23]

In addition to the delay tactics cited above, DEA has failed to follow the procedures mandated by law regarding applications such as that submitted by Prof. Craker. Although DEA is required by law to publish a notice in the Federal Register "upon the filing" of an application for registration to manufacture a controlled substance,[24] DEA did not publish a notice until July 24, 2003, more than two years after Prof. Craker's initial application.[25] The required sixty-day comment period[26] ended on September 23, 2003, the only comment being an objection filed by Prof. Mahmoud El-Sohly, Director of NIDA's University of Mississippi cannabis farm. DEA is also required by law to approve or deny applications to manufacture a controlled substance and may not deny such an application without issuing an Order to Show Cause that gives the applicant an opportunity to request an administrative hearing to present evidence and argument as to why the application should be granted.[27] DEA has not taken any of these actions.

On July 21, 2004, Prof. Craker and MAPS sued DEA for unreasonable delay in responding to Prof. Craker's appli-

[23] Letter from Sens. Edward M. Kennedy and John F. Kerry, to Karen Tandy, Administrator, DEA (Oct. 20, 2003), *available at* http://www.maps.org/mmj/kkletter102003.html.

[24] 21 C.F.R. §1301.33(a).

[25] Manufacturer of Controlled Substances – Notice of Application. 68 Fed. Reg. 43, 755 (July 24, 2003).

[26] 21 C.F.R. §1301.33(a).

[27] 21 C.F.R. §§1301.33, 1301.35, 1301.37, 1301.41, and 1301.43.

cation. As of the date of this brief's filing, even a lawsuit has not resulted in any further action on Prof. Craker's application. DEA's failure even to deny Prof. Craker's application is an unjust and unreasonable obstruction to FDA-approved scientific research and is not a hallmark of a well-functioning approval process that would ensure the protection of patients' constitutional rights.

The government has used similar delay tactics in processing the application of Chemic Laboratories, Incorporated of Canton, Massachusetts (hereinafter "Chemic") to import cannabis for a MAPS-sponsored study to evaluate the contents of the vapor stream from a cannabis vaporizer.[28] This study does not involve human subjects nor require FDA approval but will provide valuable knowledge about alternative cannabis delivery systems that might spare patients exposure to the potentially harmful elements of cannabis smoke.

On June 24, 2003, Chemic submitted separate but related applications to the U.S. Department of Health and Human Services (HHS) and DEA seeking, respectively, approval of its research protocol so that Chemic could purchase 10 grams of cannabis from NIDA, and registration to import ten grams of cannabis from the Dutch Office of Medical Cannabis (the "DOMC"), part of the Dutch Ministry of Health. The DOMC operates in compliance with all international treaty obligations and is authorized to export cannabis to fully-licensed research projects. DOMC can supply cannabis of a quality that is unavailable from NIDA and is required to complete the later phase of the vaporizer study. DEA verbally advised

[28] MAPS and California NORML are sponsoring research into the use of vaporizer technology to heat the cannabis plant but not burn it. Preliminary evidence demonstrates that the vaporizer can release clinically significant amounts of cannabinoids without generating the compounds that come from combustion. This is part of an effort to develop non-smoking delivery systems for the cannabis plant.

Chemic that it would not process the application until HHS determines the scientific merit of the vaporizer protocol. DEA has also failed to publish a notice in the Federal Register, as is required by statute "upon the filing" of an import application, which is necessary to begin the 60-day comment period.[29]

HHS has failed to decide upon the scientific merit of the research protocol for over fifteen months. HHS's first communication to Chemic with respect to its application came on October 10, 2003, more than three months after it was submitted, stating that there was insufficient information in the application to judge the merits of the protocol. Although the application had complied fully with HHS's announced procedures, Chemic submitted an expanded and revised protocol on January 29, 2004. In the months after this submission, Chemic has made repeated attempts to ascertain the status of its application, which HHS officials have refused to divulge. On March 17, 2004, Rear Admiral, Assistant Surgeon General and Deputy Assistant Secretary for Health (Operations) Arthur J. Lawrence communicated via email that the application was awaiting only the HHS's required Public Health Service intermediate review process, but he could not say when that would occur.[30] He has subsequently ignored all further inquiries.

In contrast, pursuant to 21 C.F.R. § 1301.32(a), HHS review of applications and protocols submitted to it by DEA in the case of application for registration to conduct non-clinical research (such as Chemic's protocol), must be completed

[29] 21 C.F.R. §1301.34(a).

[30] Email exchange between Dr. Arthur J. Lawrence, Rear Admiral, Assistant Surgeon General and NIDA Deputy Assistant Secretary for Health (Operations), and Willem Scholten, Head of the Dutch Office of Medicinal Cannabis (Mar. 17, 2004), *available at* http://www.maps.org/mmj/vaporizer.html.

within 21 days after receipt of the application and complete protocol. In further contrast, FDA is required to review much more complicated protocols involving human subjects within 30 days.[31]

On June 9, 2004, MAPS received a letter from NIDA that is perhaps the most telling evidence of the futility of pursuing medical cannabis research under the current regulatory system. In this letter, NIDA Director Dr. Nora Volkow explained that

> As you know, NIDA is just one of the participants on the HHS review panel . . . It is not NIDA's role to set policy in this area . . . Moreover, it is not NIDA's mission to study the medicinal uses of marijuana or to advocate for the establishment of facilities to support this research. Therefore, I am sorry but I do not believe that we can be of help to you in resolving these concerns.[32]

These statements highlight the chilling effect that the NIDA monopoly has on research that could demonstrate how medical cannabis can be used to help sick Americans.

On July 14, 2004, MAPS and Valerie Corral[33] filed a lawsuit against both HHS and DEA alleging unreasonable delay in processing Craker's and Chemic's applications. Even after being sued, neither HHS nor DEA has offered any further information regarding the protocol and application.

Given such executive branch obstructionism, the UMass Amherst facility will likely require several years or more to become approved and operational, if it ever can. Attempts to

[31] *See* 21 C.F.R. § 312.20 (c).

[32] Letter from Dr. Nora Volkow, Director of NIDA, to Rick Doblin, President of MAPS (June 9, 2004), *available at* http://www.maps.org/mmj/mmjfacility.html.

[33] Valerie Corral is a California-licensed medical cannabis patient and caregiver and founder of the Wo/Men's Alliance for Medical Marijuana with an office at 230 Swanton Road, Davenport, California.

import cannabis for studies that would substantially contribute to the body of scientific knowledge regarding medical cannabis and its delivery have also been obstructed. For the foreseeable future, NIDA will continue to exert undue control over medical cannabis research as a result of its monopoly over the supply of cannabis, leaving suffering patients little recourse other than asserting their constitutional rights.

C. HHS's 1999 Guidelines Restrict Rather than Facilitate FDA-Approved Research.

In December 1999, HHS finally implemented a new written policy regarding the provision of cannabis to FDA-approved researchers, allegedly to expedite FDA-approved medical cannabis research.[34] However, rather than fulfilling its stated intent to facilitate research, HHS's new policy made research more difficult by adding yet another bureaucratic layer to the process.

HHS's guidelines require sponsors of privately funded and FDA-approved protocols who seek to purchase supplies from NIDA to submit their protocols for review and approval to the Public Health Service (PHS), an additional review process that exists exclusively for cannabis research.[35] HHS guidelines also specified a limited number of medical conditions for which cannabis should be tested, recommended that protocols be designed to prove cannabis equal or superior to existing medications despite FDA's statutory requirement to approve drugs if they are proven safe and efficacious as compared to placebo (since some patients may respond best to a medicine that is not on average equal to or better than

[34] Department of Health and Human Services, Guidance On Procedures for the Provision of Cannabis for Medical Research (1999), *available at* http://www.mpp.org/guidelines/hhsguide.html.

[35] The new HHS guidelines read, "After submission, the scientific merits of each protocol will be evaluated through a Public Health Service interdisciplinary process." *Id.*

other medicines), suggested that researchers conduct only "multi-patient" studies rather than "single-patient" studies which FDA also considers scientifically valid, and discouraged researchers from conducting studies with the goal of getting natural cannabis approved as a prescription medicine.[36] None of these restrictions apply to research with any other substance, even those in Schedule I. Especially problematic, the HHS guidelines establish no time limits within which HHS must evaluate protocols submitted to it for review.

Almost immediately, HHS's policy had a chilling effect on medical cannabis research. In September 1999, Dr. Ethan Russo received FDA approval for a protocol designed to examine the medical uses of cannabis in treatment-resistant migraine patients, an indication for which cannabis was utilized in mainstream Western medicine between 1842 and 1942.[37] In February 2000, NIDA refused to supply Dr. Russo with the necessary cannabis, based on criticisms of the protocol design by the PHS reviewers.[38] Since Dr. Russo's protocol was approved by FDA and would have been privately funded, the decision by PHS and NIDA not to provide the cannabis at cost effectively halted the standard FDA drug development process. As noted above, Chemic's HHS application also is currently stalled at the PHS stage, according to a NIDA official. Were it not for this additional

[36] *Id.*

[37] Letter from C. McCormick, Director of FDA Division of Anesthetics, Critical Care and Addiction Drug Products, to Dr. Ethan Russo (Sept. 21, 1999). *See also* Ethan Russo, *Cannabis for Migraine Treatment: The Once and Future Prescription?* 36 Pain, Jan.1998, at 3-8, *available at* http://www.druglibrary.org/crl/pain/Russo%2098%20Migraine_%20Pain.pdf.

[38] Letter from Steven W. Gust, Ph.D., Special Assistant to the Director of HHS, Public Health Service, to Dr. Ethan Russo (Feb. 1, 2000), *available at* http://www.maps.org/mmj/russo1199/02010001.html.

bureaucratic layer, HHS might have already issued a decision on the protocol's merits.

Clearly, these guidelines have not served to facilitate medical cannabis research. John Benson, M.D., principal investigator of the 1999 IOM report on medical cannabis, commented that "it's hard to discern that these guidelines have streamlined existing procedures."[39] For the foreseeable future, medical research with cannabis will proceed only as far and as fast as NIDA and HHS permit, regardless of the willingness of FDA to allow clinical trials to move forward.

D. HHS's Policy Makes it More Difficult to Research Cannabis Than Any Other Drug, Including All Other Schedule I Drugs.

Within the last ten years, FDA has approved several privately funded protocols involving the use of Schedule I substances such as MDMA (Ecstasy),[40] psilocybin,[41] and ibogaine. [42] Each of these studies has been or is being

[39] P. McMahan, *Oregon, Alaska Identify Legal Marijuana Users on State-Issued Cards*, USA Today, May 24, 1999, at A4.

[40] Approved November 5, 1992. Investigational New Drug (IND) #39,383. A Phase 1 dose- response safety study conducted by Dr. Charles Grob, Harbor UCLA. Approved November 2, 2001. IND #63,384, A Phase II pilot study conducted by Dr. Michael Mithoefer, Charleston, SC. The MDMA for both studies was manufactured under DEA license by Dr. David Nichols, Dept. of Medicinal Chemistry, Purdue University.

[41] IND # 56,530. Letter from C. McCormick, Director of FDA's Division of Anesthetics, Critical Care and Addiction Drug Products, to Dr. Francisco Moreno (Sept. 17, 1998). This protocol was approved but put on hold until a source of psilocybin could be arranged. MAPS arranged for Organix, Inc. of Woburn, MA to manufacture the psilocybin, with approval from DEA and FDA. This study is now in progress.

[42] On August 25, 1993, the FDA Drug Abuse Advisory Committee meeting recommended approving the Phase 1 dose- response safety study proposed by Dr. Juan Sanchez-Ramos and Deborah Mash, Ph.D.,

conducted with compounds obtained from private, non-governmental DEA-licensed manufacturers. The lack of an independent source of cannabis for use in FDA-approved clinical trials is an aberration and not the norm for Schedule I drugs.

E. Given the Difficulty of Conducting FDA-Approved Research, It is Unlikely that the FDA Will Be Able to Approve Cannabis as a Prescription Medicine in the Near Future, If Ever.

Despite high interest among doctors and medical researchers in developing cannabis for FDA-approved prescription use to treat serious illness, the federal government has placed so many obstacles in the way of that development that it is unlikely we will see any significant progress in the near future. The IOM, in a 1999 report commissioned by the White House Office of National Drug Control Policy to study the therapeutic uses of cannabis, noted that "it would likely be many years" before a safe and effective system of medical cannabis delivery would be available to patients.[43] IOM attributed the current lack of scientific study of medical cannabis to "a daunting thicket of regulations at the federal level" [44] and cited the "rigors of obtaining an adequate supply of legal, standardized marijuana for study"[45] as one of the challenges plaguing scientific research in this field. Nonetheless, HHS, DEA, and NIDA continue to obstruct research that would increase the body of knowledge about

University of Miami Medical School. The ibogaine for this study was imported by the researchers from Europe, with DEA approval.

[43] Institute of Medicine, Cannabis and Medicine: Assessing the Science Base, 7-8 (J. Joy, S. Watson, J. Benson, eds., 1999), *available at* http://stills.nap.edu/books/0309071550/html, pp. 7-8.

[44] *Id.* at 137.

[45] *Id.* at 217.

medical cannabis and its delivery, despite the fact that, as the IOM report notes, it is "widely used" by certain patient groups despite the uncertainty.[46]

Consequently, patients who are already medicating with cannabis under their doctors' supervision have little hope that the FDA drug-approval process will result in cannabis being made available as a prescription medicine. This pessimistic outlook has nothing to do with the actual therapeutic potential of cannabis and has everything to do with political obstacles that have subverted the FDA drug-approval process.

F. The Executive Branch Has Also Prevented Patients From Obtaining Relief by Participating in Single-Trial Studies, Contrary to the Recommendations of the Institute of Medicine.

The IOM suggested in its 1999 report that a possibility for helping patients currently suffering who might benefit from medical cannabis would be to allow them to participate in single-patient clinical trials, "in which patients are fully informed of their status as experimental subjects using a harmful drug delivery system, and in which their condition is closely monitored and documented under medical supervision." [47] IOM makes this recommendation in acknowledgment of the fact that there is "no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana" and outlines several limiting conditions upon the population who would be eligible for participation in such studies.[48]

[46] *Id.* at 7.

[47] *Id.* at 7-8.

[48] *Id.*

However, HHS's policy as announced in its medical cannabis research guidelines, which formally took effect in December 1999, does not allow for this possibility despite IOM's recommendation. HHS's policy reads, in part:

> HHS intends to direct its program toward multi-patient clinical studies. As previously determined by [PHS], single-patient requests for marijuana raised a number of concerns including the fact that the single-patient IND process would not produce useful scientific information and we do not foresee that they would be supported under this program.[49]

Hence, the executive branch has not only shown its willingness to block congressional intent, but it has also disregarded the findings of the IOM of the National Academy of Sciences, chartered by Congress in 1863 to advise federal agencies. The result of this choice is that patients continue to suffer from debilitating conditions and must assert their constitutional rights to obtain relief.

II. BECAUSE THE FDA DRUG DEVELOPMENT PROCESS IS NOT WORKING AS CONGRESS INTENDED, PATIENTS WHO FOLLOW THEIR DOCTORS' ORDERS TO OBTAIN CANNABIS THROUGH ALTERNATIVE MEANS SHOULD BE PERMITTED TO ASSERT THEIR CONSTITUTIONAL RIGHTS TO USE CANNABIS

The Court should not rule against patients' constitutional rights to use cannabis based on the illusion of a well-functioning FDA-approval process. Pursuing legitimate, privately funded clinical research with cannabis is more burdensome than engaging in research with any other drug. As the Court considers the viability of patients' constitutional

[49] Department of Health and Human Services, Guidance On Procedures for the Provision of Cannabis for Medical Research (1999).

rights to use cannabis, it should consider that the lack of sufficient scientific data from FDA-approved controlled clinical trials to justify FDA-approval of cannabis as a prescription medicine is due in large part to the hindrance of research over the last several decades.

MAPS is a privately-funded research organization whose mission involves developing cannabis into an FDA-approved prescription medicine. Its mission has been sabotaged by its inability to obtain an independent source of supply of cannabis to use in its research. MAPS's offer to contract with NIDA's cannabis producer for supplies of cannabis that could be used in FDA-approved research was rejected, Prof. Craker's MAPS-sponsored application to DEA for a license to grow cannabis has not been responded to in over three years, and Chemic's MAPS-sponsored applications to DEA to import and to NIDA to purchase 10 grams of cannabis for further vaporizer research have not been responded to in over fifteen months. MAPS cannot contract, produce, import or purchase cannabis for its research efforts. As a result of these obstructions, MAPS has resorted to filing suit against DEA and HHS/NIH/NIDA, claiming unreasonable delay under the Administrative Procedures Act.

Thousands of seriously ill patients whose physicians consider their use of cannabis to be medically necessary for the treatment of their illnesses must risk criminal sanctions to obtain the relief they deserve. Many—if not all—of these patients would prefer to receive their medication through pharmacies. Short of that, many patients would appreciate the opportunity to participate in FDA-approved research as a means of gaining temporary, legal access to cannabis. Having been thwarted by bureaucratic obstacles impeding recourse through the FDA, medical cannabis patients currently have no practicable option but to assert their constitutional rights to use cannabis. Given the difficulties of conducting FDA-approved research into the medical uses of cannabis because

of past and continuing supply problems and HHS's unique and restrictive guidelines, it is unrealistic to expect that patients who have a legitimate medical need will be able to obtain legal access to cannabis via FDA-approved research in any substantial way at any point in the near future. Patients must therefore assert their constitutional rights to protect their lives and health from a governmental process that is not functioning as Congress intended.

CONCLUSION

For the foregoing reasons, Amici ask this Court to affirm the judgment of the court of appeals.

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